

Patent
Customer No.: 006980
Docket No.: GOY4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)	Confirmation No.: 5611
)	
GOYARTS, Gregorius M. H.)	Group Art Unit: 1794
)	
Serial No.: 10/551,781)	Examiner: Khatri, P. J.
)	
Filed: 5 October 2005)	
)	
For: WASHABLE UNDER PAD AND METHOD FOR)	
PRODUCING AN UNDER PAD OF THIS TYPE)	

37 CFR § 1.132 DECLARATION OF DAVID SCHREINER

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Atlanta, GA 30308
17 December 2010

Dear Honorable Sir:

1. I acknowledge, under the penalty of perjury pursuant to 18 U.S.C. § 1001, that willful false statements and the like are punishable by fine or imprisonment, or both, and may jeopardize the validity of the above identified patent application or any patent issuing from the above identified patent application. I have personal knowledge of the statements and information contained herein. All statements made below on my knowledge are true, and all statements made below on information and belief are believed to be true. For any statements made regarding legal concepts, we have relied on legal counsel explaining such concepts to me. I make this declaration in support of the patentability of the claims pending in this Application.

2. I, David Schreiner, a citizen of Canada, residing at 5385 NDG Avenue, Montreal, Quebec, Canada, H4A 1L2 am Executive Vice-President of MIP Inc, the company to which the above-identified application has been assigned. As Executive Vice-President I am considered an expert on healthcare products, in particular on those products produced by MIP and the products of the competition.

3. MIP Inc sells healthcare products and are specialists in producing water proof absorbent products, such as pads, clothing protectors, inco garments, etc.

4. Having taken notice of the *Office Action* by the Examiner in the examination of the above identified patent application, and the art cited (Hahn et al. US 5306267 and Levy US 5114418 in particular) I hereby opine that diapers and under pads (also known as bed pads) are non-related products to those of skill in the art.

5. Reusable cloth diapers (see picture) are body worn devices for incontinence that are shaped appropriately to conform to the contour of the body. They may be worn by adults, children and babies, which tend to be mobile. Diapers are therefore anatomically designed to snugly fit the body with freedom to move the legs while keeping the diaper firmly affixed around the waste. In terms of comfort, freedom of movement is important. Generally, reusable cloth diapers have a narrow and thick crotch region that is composed of many layers to absorb the urine and fecal spills. It is not uncommon for the spill region to be around at least ½ inch thick or more.



6. Under pads, on the other hand, are not body worn but instead used as linen protectors. They are flat and typically rectangular in shape. They are used for instance in hospitals, nursing homes and retirement homes, where incontinence may be a problem and/or where linen need to be protected for other reasons. They have a variety of applications within a healthcare environment above and beyond incontinence. On the other hand, their use is preferably unnoticed. For this reason they tend to be of similar dimensions (width) as the mattress they are to protect, without affecting the comfort of the mattress. Moreover, for bedridden patients it is important that they absorb any spills that may lead to bed sores (decubitis). Bed sores may be caused by many factors such as: unrelieved pressure; friction; humidity; shearing forces; temperature; age; incontinence and medication; to any part of the body, especially portions over bony or cartilaginous areas such as sacrum, elbows, knees, and ankles. Many of these issues are discussed in Exhibit A. In the UK, The Royal College of

Nursing has published guidelines in 'Pressure ulcer risk assessment and prevention'. These guidelines are included as Exhibit B. On page 20 it is clearly indicated that

"Incontinence is often said to increase the risk of developing pressure ulcers. ...

The key factor is moisture to the skin, which puts it at greater risk from maceration, friction and shearing forces. Therefore the key practice issue is the presence or absence of wet skin (Defloor, 1999). As such, effective management of incontinence is an essential part of skin care and fundamental to maintaining a person's dignity and comfort.

Where the source of moisture cannot be controlled, the use of moisture-absorbing or continence aids could be considered. **The use of such aids should not interfere with any pressure redistributing surface an individual may be placed on.**" (Emphasis added).

7. Exhibit C is a document produced on my behalf with pictures illustrating the history and the current state of the art on under pads. The closest state of the art with respect to the invention defined in the above-identified application are quilted under pads. Such under pads are currently commercially sold, as shown in Exhibit D (copies of adverts on the internet). As is shown in Exhibit C, the quilted under pads are relatively thin and of similar dimensions (width) of the mattress. Also shown in Exhibit C is that the quilted under pads suffer from roll over, pilling, wrinkling, and movement within the layers. This may cause shear, which should actually be prevented.

8. A brief description of the documents being submitted is as follows:

a. A copy of an article (Exhibit A), dated September 2009, entitled Protecting What Matters: DermaCare Fusion Stay Dry Technology.

b. A copy of an article (Exhibit B), dated April 2001, entitled "Clinical Practice Guidelines", by the Royal College of Nursing. The Exhibit remarks on the importance that moisture-absorbing or continence aids should not interfere with any pressure redistributing surface that an individual may be placed on (page 20, right column).

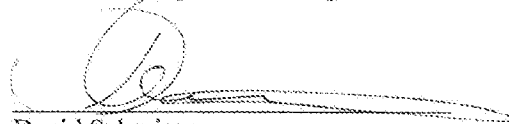
c. A copy of a document prepared by MIP on the History of under pads (Exhibit C). The pictures disclosed therein illustrate problems such as roll over, pilling, wrinkling and movement within layers.

d. Copies of internet adverts on reusable under pads (Exhibit D). These adverts provide typical information on commercial, quilted under pads.

9. The above-referenced exhibits establish that reusable body-worn diapers and the more generally applicable reusable under pads of the current invention are non-related products. For these reasons, a person skilled in the art would not consider reusable diapers when setting out to find a reusable under pad that outperforms the commercial, quilted under pads.

Dated: _____

17/12/2010



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PROTECTING WHAT MATTERS: DermaCare Fusion Stay Dry Technology

Abstract

Maintaining skin integrity is a critical component in the care of the hospitalized patient today. Understanding the impact of methods to maintain skin integrity is vital toward the prevention of skin breakdown. The use of a high quality reusable underpad is beneficial to the patient in the acute care setting because of its ability to promote skin integrity while protecting bed linen underneath. This paper will explore the specific clinical advantages of the reusable underpad that incorporates new fabric technologies providing enhanced incontinence management.

Introduction

One of the major concerns in hospitals today is the development of hospital-acquired pressure ulcers. Pressure ulcers are injuries resulting from extended pressure interrupting blood flow to the skin, causing problems ranging from discoloration, loss of sensation and scarring to full-fledged skin loss and tissue damage. An estimated 7% of all hospital patients are at risk of developing pressure ulcers over the course of their stay.

Prevalence

Pressure ulcers are a potential complication of prolonged bed rest, particularly for the elderly and incontinent patients who are especially prone to skin breakdown if moisture is not appropriately managed.

Skin breakdown occurs most often on the sacrum, perineum, coccyx/buttocks and heels. Patients with fecal incontinence are 22 times more likely to develop pressure ulcers than if they did not have this condition.

According to Michelle Beaver, The Centers for Medicare and Medicaid Services (CMS) reported in 2007 there were over 250,000 cases of Stage III and IV pressure ulcers that developed in the hospital and resulted in additional treatment cost of \$43,000 per hospital stay. Stage III and IV pressure ulcers are among the 10 categories of hospital-acquired conditions (HAC) with payment implications effective October 2008.

Prevention

Linen products play a key role in the prevention of pressure ulcers. It is important clinicians minimize exposure of the patient's skin to moisture by assessing and treating incontinence at the time of occurrence.

Using an underpad with good wicking and absorption capabilities is essential. Constant exposure to wetness can macerate or waterlog the skin. Maceration is a contributing factor in the etiology of pressure ulcers primarily because the excessive moisture softens the connective tissue and, once macerated, the epidermis is more easily eroded.

Eventually, degenerative changes occur and the tissue sloughs. Moist skin is five times as likely to become ulcerated as dry skin. Therefore it is important to maintain as dry a surface as possible under the patient.

Industry Response

With increased awareness of the need to prevent ulcers, healthcare product manufacturers have made recent technological improvements in both reusable and disposable underpads. These improvements focus on softer, more absorbent materials and construction techniques that enhance air flow and help maintain the position and shape of the underpad.

Multi-layer composition promotes air circulation under the patient and maintains body temperature without heat buildup. When determining the correct product choice to contain incontinence, it is important to assess the textile components.

A top layer, or the "facing," constructed of specifically designed 100% synthetic fabric is comfortable next to the skin and quickly absorbs moisture, pulling it into the middle "soaker" layer. A polyester/rayon soaker continues to absorb fluid after the initial void. A "barrier" layer on the bottom of the underpad constructed of brushed polyurethane is 100% impermeable and keeps the pad securely in place without bunching up. DermaCare Fusion's construction allows for no movement between layers, hence minimizing potential sheer for fragile skin.

Proper Protocol

Each layer of linen on a hospital bed should be designed to promote skin integrity and patient comfort.

Thin profile bonded underpads are designed to lie flat under the patient to minimize potential pressure points and do not affect the performance of pressure redistribution surfaces.

Incontinent pads should be large enough to ensure sufficient protection for the patient and the bed linen. Use one underpad at a time to help contain incontinence, as there is no added benefit to layering of underpads. Multiple layers could create pressure points thus potentially contributing to skin breakdown.

Stay Dry Technology

It is essential the most effective product is chosen to help ensure the integrity of the patient's skin and help prevent skin breakdown.

DermaCare Fusion's "Stay Dry" technology features distinct characteristics to promote skin care: rapid wicking, minimal liquid reflux (the counterpart to fluid retention) and high absorbency.

Wicking allows the moisture to spread away from the body. Rapid wicking translates into a shorter exposure of the skin to moisture. Liquid reflux is the weight of liquid that may get transferred from the soaker to the surface once pressure is applied (i.e. patient lying in bed). It is in direct proportion with the fluid retention capacity of the soaker layer. The lower the volume of liquid reflux, the drier the skin.

Lastly, absorbency is measured by both quantity of fluid and time needed for liquid to be absorbed. In the case of reusable underpads, it is important to note they will retain their absorption characteristics even after one void. With disposables it has often occurred following the first void the absorbent polymers are no longer able to absorb a second episode.

Environmental Considerations

Environmental concerns are also key. In an article presented by Practice Greenhealth, "America's hospitals generate 6,600 tons of waste each day. Hospitals that have chosen to use disposable products rather than reusables produce a substantially greater amount of solid and medical waste, costing them more in disposal costs."

The American Hospital Association and the United States Environmental Protection Agency signed a Memorandum of Understanding to reduce healthcare waste by 50% in 2010.

Conclusion

While patient care is paramount, hospitals must balance financial concerns. DermaCare Fusion provides a cost-savings, eco-friendly alternative to disposable incontinent pads staying focused on patient safety, comfort and dignity.

Beaver, Michelle, "CMS to Put Pressure on Providers for Decubitus Ulcer Prevention", Infection Control Today, 08/04/08

PracticeGreenhealth.org; Reusable vs. Disposable Textiles; <http://cms.h2e-online.org/ee/waste-reduction/waste-minimization/textile/reusedispose/>

EPA-AHA Memorandum of Understanding available at <http://www.cghenvironmental.com/memorandum.html>

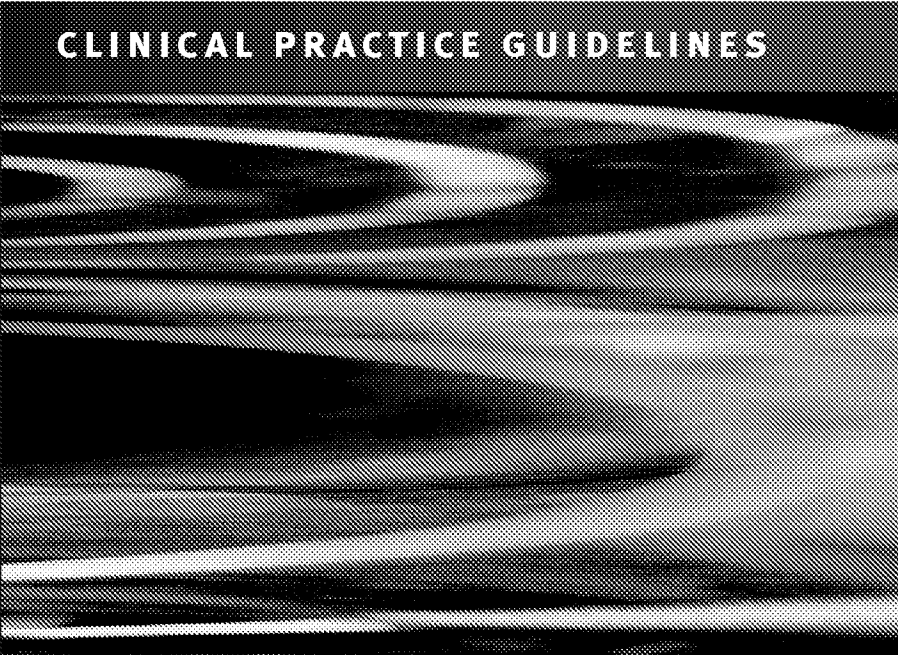
Centers For Medicare and Medicaid; http://www.cms.hhs.gov/HospitalAcqCond/06_Hospital-Aquired.asp

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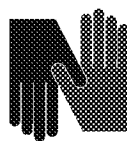
improving practice:
improving care

CLINICAL PRACTICE GUIDELINES



Pressure ulcer risk assessment and prevention

RECOMMENDATIONS 2001



Royal College
of Nursing

Pressure ulcer risk assessment and prevention

Recommendations

2001

The Department of Health commissioned the RCN Institute to develop a Pressure Ulcer Guideline prior to the establishment of the National Institute for Clinical Excellence. This is one of the inherited guidelines on the Institute's programme.

The guidance published by NICE (www.nice.org.uk) on pressure ulcer risk assessment and prevention is derived from this clinical guideline.

Contributors to the guideline's development

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for research papers

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Introduction

"I had an operation on my gall bladder. I told the staff I was prone to getting pressure sores. They assured me I would not get any while in their care. Low and behold when I came around from the anaesthetic, they found a beauty...it is now six and a half years old"

(person with a spinal injury)

Background

Pressure ulcers represent a major burden of sickness and reduced quality of life for patients and their carers (Franks *et al*, 1999). The financial costs to the NHS are also substantial (Cullum *et al*, 1995). It has been estimated that preventing and treating pressure ulcers in a 600-bed general hospital costs between £600,000 and £3 million a year (Touche Ross, 1993). Collier, 1999a, applying a similar formula to Hibbs, 1988, calculated the cost of treating a patient with a Grade IV pressure ulcer as £40,000.

Pressure ulcers, also known as pressure sores, decubitus ulcers and bedsores, are areas of localised damage to the skin and underlying tissue. They are thought to be caused by a combination of pressure, shear and friction (Allman, 1997). Collier, 1996, defines them as:

"...skin ulceration as a result of pressure in combination with the effects of other variables"

Acute illness/trauma and immobility are key variables but others identified in the proceeding recommendations, are also believed to play a part

Pressure ulcers usually occur over bony prominences and should be graded or staged to classify the degree of tissue damage observed. Unfortunately they are a common occurrence. A well-quoted study found new pressure ulcers occurring in 4 to 10% of patients admitted to a UK District General Hospital (Clark and Watts, 1994), dependent upon the patient case mix.

The human and financial cost of pressure ulcers, together with a variation in practice across the UK and a growing body of knowledge about effectiveness, have highlighted the need for recommendations for practice.

In response, the NHSE commissioned the Royal College of Nursing (RCN) to produce an evidence-linked clinical guideline on risk assessment and prevention of pressure ulcers. The guideline complements and builds on the work of others, such as the *European Pressure Ulcer Prevention Guidelines* (EPUAP, 1999).

The guidelines

The guidelines provide health care professionals with recommendations which:

- ◆ help early identification of patients at risk of developing pressure ulcers
- ◆ suggest preventive interventions
- ◆ point out practice that may be harmful or ineffective.

The guideline's overall aim is to help reduce the occurrence of pressure ulcers. It comprises six sections:

- ◆ **Quick reference guide** and summary of recommendations
- ◆ **Philosophy of care** which makes suggestions about the environment within which the recommendations should be implemented
- ◆ **Evidence-linked recommendations** for:
 - identifying individuals at risk
 - use of risk assessment scales
 - recognising risk factors
 - skin inspection
 - pressure redistributing devices
 - use of aids
 - positioning
 - seating
 - education and training.
- ◆ **Essentials of care** which identifies the practice issues of nutrition, continence management and hygiene and their role in pressure ulcer development
- ◆ **Quality improvement** which includes a quality improvement cycle, monitoring, discharge planning, and audit information
- ◆ **Glossary of terms**

The guideline does not cover the epidemiology of pressure ulcers or make recommendations for wound care and/or the surgical management of pressure damage.

Intended users of the guideline

To provide a co-ordinated approach, risk assessment and prevention of pressure ulcers should be seen as an inter-disciplinary issue.

This guideline is intended to be used by all health care staff including: managers, professionals allied to medicine, nurses, doctors, equipment suppliers and academics. It could also be adapted for use by patients and carers.

Patients and settings

The recommendations are for patients (adults and children) who have no pressure ulcers, seen in hospital, nursing homes, supported accommodation and at home. They do not include treatment of existing pressure ulcers.

However, in cases where a patient has a pressure ulcer, they will be useful in preventing pressure ulcers on other areas of the body. Patients (adults and children) are referred to as individuals, persons or users throughout the guideline.

Overview of guideline development method

A project officer developed the guideline in collaboration with an inter-disciplinary group, including users and carers.

See Appendix 1 for a brief overview of the method.

Full details about the development of the guideline can be found in the *Technical Report* (Rycroft-Malone and McInnes, 2001), the definitive document which includes method and recommendations (available at www.rcn.org.uk).

Evidence considered for this guideline has come from a number of sources:

- ◆ the Agency for Health Care Policy and Research (AHCPR, 1992) evidence-linked guideline *Pressure ulcers in adults: prediction and prevention*
- ◆ an update of sections of their research base (Rycroft-Malone and McInnes, 2000)
- ◆ the Effective Health Care Bulletin *The prevention and treatment of pressure sores* (EHCB, 1995)
- ◆ a systematic review of the effectiveness of pressure redistributing devices (Cullum *et al*, 2000)
- ◆ a systematic review of the effectiveness of risk assessment tools (McGough, 1999)
- ◆ the results of a formal consensus process (Rycroft-Malone, 2000).

As the above indicates, two clinical issues have recently been the subject of systematic review: risk assessment scales (McGough, 1999) and pressure redistributing devices (EHCB, 1995; Cullum *et al*, 2000). Their results provided some evidence that could be translated into recommendations. Both authors reported on the poor quality of the studies available for review and highlighted the need for good quality research in these areas.

The AHCPR guideline (1992) included a literature review of topics such as skin care, positioning and education. An updated literature review of these areas (1991-1998) revealed little good research evidence had emerged in the interim period (Rycroft-Malone and McInnes, 2000). In the light of this, a formal consensus development process was used to integrate the different evidence sources and, where there was a weak research base, agree recommendations based on current best practice.

Evidence base

The guideline is evidence-linked, rather than evidence-based. As there was insufficient evidence to guide all clinical decisions, a number of recommendations for practice were solely or partially based on consensus expert opinion. The recommendations were graded as follows:

- I Generally consistent finding in multiple acceptable studies**
- II Either based on a single acceptable study, or a weak or inconsistent finding in multiple acceptable studies**
- III Limited scientific evidence which does not meet all the criteria of acceptable studies or absence of directly applicable studies of good quality. This includes expert opinion.**

(adapted from Waddell *et al*, 1996)

(‘acceptable’ for this guideline refers to those that have been subjected and approved by a process of critical appraisal, see Technical Report for more details).

Additionally, some recommendations have figures next to them. These show the results of the formal consensus process – for example: (m 9, iqr 1.25). They refer to the median (m) and inter-quartile range (iqr) calculated from the consensus ratings. In this example, 9 was median (or average) rating, and an inter-quartile range

of 1.25 tells us that not everyone rated 9 – that is there was a distribution of scores. If everyone rated 9 the inter-quartile range would be 0. The larger the inter-quartile range, the lower the level of agreement within the group. Although these are consensus-rating scores, the group did consider research evidence together with their clinical opinion/expertise to make these judgements.

The evidence grade shows the type of evidence supporting each recommendation though it does not indicate the strength of each recommendation. All recommendations are endorsed equally and none are regarded as optional.

Guidance is provided for local application for recommendations where there is little available research, or where a review of the research has been inconclusive in its findings. For example, because the systematic review of risk assessment scales suggested a limited use and did not identify the superiority of one scale over another for predicting pressure ulcer development, the choice whether or not to use one is left up to individual health care delivery services.

Updating of the guideline

The guideline was completed in Spring 2000. Resources permitting, the guideline would be reviewed and updated on a two-yearly basis by the RCN. The first revision would therefore begin in 2002.

Audit

Simple audit criteria are included in the section on Quality Improvement. They have been developed from the recommendations and may help in developing a local audit tool. The criteria require further development work and piloting.

Disclaimer

As with any clinical guideline, recommendations may not be appropriate for use in all circumstances. Clearly a limitation of a guideline is that it simplifies clinical decision-making (Shiffman, 1997). Decisions to adopt any particular recommendations must be made by the practitioner in the light of:

- ◆ available resources
- ◆ local services, policies and protocols
- ◆ the patient's circumstances and wishes
- ◆ available personnel and equipment
- ◆ clinical experience of the practitioner
- ◆ knowledge of more recent research findings.

Quick reference guide

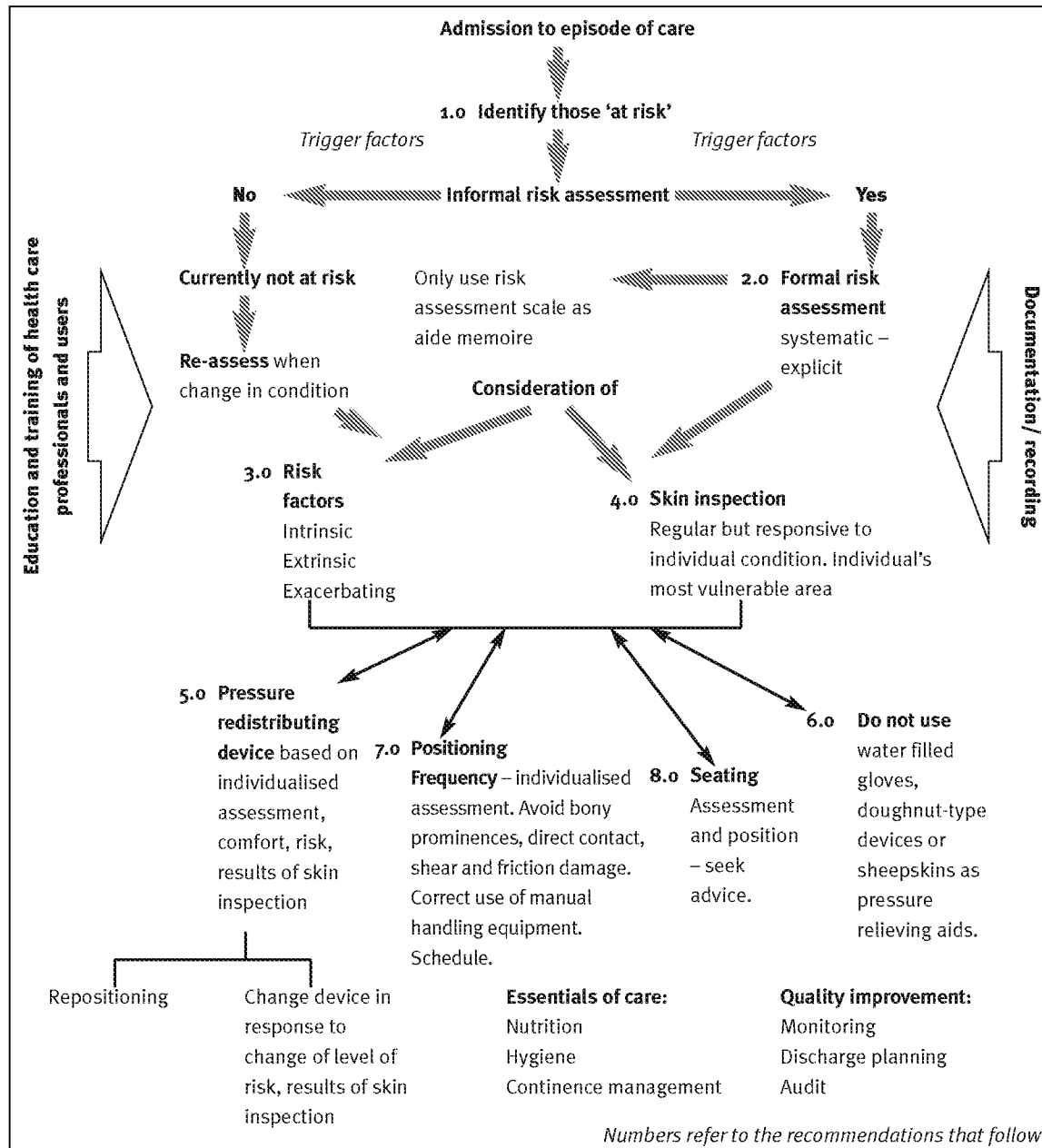


Figure 1. Quick Reference Guide

Summary of recommendations

1.0 Identifying individuals 'at risk'

- 1.1 Assessing an individual's risk of developing pressure ulcers should involve both informal and formal assessment procedures. III
- 1.2 Risk assessment should be carried out by personnel who have undergone appropriate and adequate training to recognise the risk factors that contribute to the development of pressure ulcers and how to initiate and maintain correct and suitable preventive measures. III
- 1.3 The timing of risk assessment should be based on each individual case. However, it should take place in under six hours of the start of admission to the episode of care. III
- 1.4 If considered not at risk on initial assessment, reassessment should occur if there is a change in an individual's condition. III
- 1.5 All formal assessments of risk should be documented/recorded and made accessible to all members of the inter-disciplinary team. III

2.0 Use of risk assessment scales

- 2.1 Risk assessment tools should only be used as an aide memoire and should not replace clinical judgement. I
- 2.2 If use of a risk assessment tool is preferred, it is recommended that a scale that has been tested for use in the same specialty is chosen. III

3.0 Risk factors

- 3.1 An individual's potential to develop pressure ulcers may be influenced by the following intrinsic risk factors which therefore should be considered when performing a risk assessment: reduced mobility or immobility; sensory impairment; acute illness; level of consciousness; extremes of age; vascular disease; severe chronic or terminal illness; previous history of pressure damage; malnutrition and dehydration. II
- 3.2 The following extrinsic risk factors are involved in tissue damage and should be removed or diminished to prevent injury: pressure; shearing and friction.
- 3.3 An individual's potential to develop pressure ulcers may be exacerbated by the following factors which therefore should be considered when performing a risk assessment: medication and moisture to the skin.

4.0 Skin inspection

- 4.1 Skin inspection should occur regularly and the frequency determined in response to changes in the individual's condition in relation to both deterioration or recovery. III
- 4.2 Skin inspection should be based on the individualised assessment of the most vulnerable areas of risk and therefore may include different or more areas which require inspection than those identified here: heels; sacrum; ischial tuberosities; parts of the body affected by anti-embolic stockings; parts of the body where pressure, friction and shear is exerted in the course of an individual's daily living activities; parts of the body where there are external forces exerted by equipment and clothing; elbows; temporal region of skull; shoulders; back of head and toes.
- 4.3 Individuals who are willing and able should be encouraged, following education, to inspect their own skin.
- 4.4 Individuals who are wheelchair users should use a mirror to inspect the areas that they cannot see easily or get others to inspect them.

- 4.5 Health care professionals should be vigilant to the following signs which may indicate incipient pressure ulcer development: persistent erythema; non-blanching erythema; blisters; discolouration; localised heat; localised oedema and localised induration. In those with darkly pigmented skin: purplish/bluish localised areas of skin; localised heat which, if tissue becomes damaged, is replaced by coolness; localised oedema and localised induration.
- 4.6 Any skin changes should be documented/recorded immediately.

5.0 Pressure redistributing devices

- 5.1 Decisions about which pressure redistributing device to use should be based on an overall assessment of the individual and not solely on the basis of scores from risk assessment scales. Holistic assessment should include level of risk, comfort and general health state. **I**
- 5.2 'At risk' individuals should not be placed on standard foam mattresses. **I**
- 5.3 Patients at very high risk of developing pressure ulcers should be placed on alternating pressure mattresses or other high-tech pressure redistributing systems. **II**
- 5.4 Pressure redistributing overlays should be used on the operating table of individuals assessed to be at high risk of pressure ulcer development. **I**
- 5.5 To ensure continuity of preventive care, post-operative management of at risk individuals should include the use of pressure redistributing mattresses. **III**
- 5.6 Repositioning should occur when individuals are on pressure redistributing devices. **III**
- 5.7 The benefits of a pressure redistributing device should not be undermined by prolonged chair sitting. **III**

6.0 Use of aids

- 6.1 The following should not be used as pressure relieving aids: water filled gloves; synthetic sheepskins; genuine sheepskins and doughnut-type devices. **III**

7.0 Positioning

- 7.1 Individuals who are 'at risk' of pressure ulcer development should be repositioned and the frequency of reposition determined by the results of skin inspection and individual needs not by a ritualistic schedule. **III**
- 7.2 Repositioning should take into consideration other aspects of an individual's condition – for example, medical condition, comfort, overall plan of care and support surface.
- 7.3 Individuals who are considered to be acutely 'at risk' of developing pressure ulcers should sit out of bed for less than two hours.
- 7.4 Positioning of patients should ensure that: prolonged pressure on bony prominences is minimised; bony prominences are kept from direct contact with one another and friction and shear damage is minimised.
- 7.5 A written/recorded re-positioning schedule agreed with the individual, should be established for each person 'at risk'.
- 7.6 Individuals/carers who are willing and able should be taught to redistribute their own weight.
- 7.7 Manual handling devices should be used correctly in order to minimise shear and friction damage. After manoeuvring, slings, sleeves or other parts of the handling equipment should not be left underneath individuals.

8.0 Seating

- 8.1 Seating assessments for aids and equipment should be carried out by trained assessors who have the acquired specific knowledge and expertise (for example, physiotherapists/occupational therapists).
- 8.2 Advice from trained assessors with acquired specific knowledge and expertise should be sought about correct seating positions.
- 8.3 Positioning of individuals who spend substantial periods of time in a chair or wheelchair should take into account: distribution of weight; postural alignment and support of feet.
- 8.4 No seat cushion has been shown to out-perform another; therefore no recommendation can be made about which type to use for pressure redistribution purposes.

III

9.0 Education and training

- 9.1 Health care professionals should be trained/educated in pressure ulcer risk assessment and prevention.
- 9.2 Health care professionals with recognised training in pressure ulcer management should cascade their knowledge and skills to their local health care teams.
- 9.3 An inter-disciplinary approach to the training and education of health care professionals should be adopted.
- 9.4 Training and education programmes should include: risk factors for pressure ulcer development; pathophysiology of pressure ulcer development; the limitations and potential applications of risk assessment tools; skin assessment; skin care; selection of pressure redistributing equipment; use of pressure redistributing equipment; maintenance of pressure redistributing equipment; methods of documenting risk assessments and prevention activities; positioning to minimise pressure, shear and friction damage including the correct use of manual handling devices; roles and responsibilities of inter-disciplinary team members in pressure ulcer management; policies and procedures regarding transferring individuals between care settings; patient education and information giving.
- 9.5 Patients who are able and willing should be informed and educated about risk assessment and resulting prevention strategies. This strategy should include carers where appropriate.
- 9.6 Patient/carer education should include providing information on the following: the risk factors associated with them developing pressure ulcers; the sites that are of the greatest risk to them of pressure damage; how to inspect skin and recognise skin changes; how to care for skin; methods for pressure relief/reduction; where they can seek further advice and assistance should they need it; emphasise the need for immediate visits to a health care professional should signs of damage be noticed.

II

III

Philosophy of care

This philosophy of care describes the ideal context in which to implement the recommendations in this guideline.

Person-centred care

The rights of patients and their carers to be fully informed and share in decision-making is a central tenet of a number of recent policy documents – for example *The New NHS. Modern. Dependable* (DoH, 1997); *Our Healthier Nation* (DoH, 1999); and, specifically about the rights of the child, the United Nations convention (United Nations, 1991).

Involvement and partnership in care are central to the delivery of a service which responds to users' individual needs.

- ◆ Users should be made aware of the guideline and its recommendations.
- ◆ Users should be involved in all aspects of pressure ulcer risk assessment and prevention, from involvement in assessment to shared decision-making about pressure redistributing devices.
- ◆ Health professionals are advised to respect and incorporate the knowledge and experience of people who have been at long-term risk of developing pressure ulcers and have been self-managing this risk.
- ◆ Users should be informed of their risk of developing pressure ulcers, especially when they are transferred between care settings or discharged home.

A collaborative inter-disciplinary approach to care

Pressure ulcer risk assessment and prevention should be seen as an inter-disciplinary issue. Adopting a team approach requires each member of the team to take responsibility for facilitating and improving communication, sharing care and responsibility for care. Such an approach requires health care professionals to understand and respect each other's roles in the delivery of that care.

- ◆ All members of the inter-disciplinary team should be aware of the guideline and its recommendations.
- ◆ Health care teams need to articulate the role of each member in the management of risk assessment and prevention of pressure ulcers.

Organisational issues

Organisational issues influence the quality of pressure ulcer risk assessment and prevention. Health care service providers need to ensure:

- ◆ an integrated approach to pressure ulcer prevention with clear strategy and policy supported by management.
- ◆ care delivered in a context of continuous quality improvement where improvements to care following guideline implementation are the subject of regular feedback and audit.
- ◆ commitment to and availability of education and training to ensure that all staff, regardless of profession, are given the opportunity to update their knowledge base and are able to implement the guideline recommendations.
- ◆ patients are cared for by trained staff, and that staffing levels and skill mix reflect the needs of patients.

Recommendations

1.0 Identifying individuals 'at risk'

One of the first activities in preventing pressure ulcers is the early identification of individuals who are susceptible to developing them. If a person is identified as susceptible or 'at risk', it is the health care professional's duty to ensure that preventive measures are implemented. The earliest phases of pressure ulcer development may show no outward visible signs of damage. Therefore it is important that individuals 'at risk' are given an immediate prevention plan.

- 1.1 Assessing an individual's risk of developing pressure ulcers should involve both informal and formal assessment processes.

On initial contact with the health care system:

- ◆ all individuals should have an informal risk assessment, based on their clinical presentation and consideration of risk factors.

Trigger factors which identify a susceptible individual – for example immobility, acute illness or trauma, altered level of consciousness (see 3.0 Risk factors for further triggers) – will alert practitioners to conduct a full:

- ◆ formal assessment, where an individual's risk is systematically and explicitly conducted via a structured risk assessment framework. Formal assessments should be routine for all in-patients (m 9, iqr 1.5) and all those seen on domiciliary visits (m 7, iqr 4.5).

- 1.2 Risk assessment should be carried out by personnel who have undergone appropriate and adequate training to recognise the risk factors that contribute to the development of pressure ulcers and how to initiate and maintain correct and suitable preventive measures.

Traditionally, the preferred member of the team to perform the risk assessment has been a trained nurse who has the acquired specific knowledge and expertise (m 9, iqr 0). However, if training has been completed, and knowledge and expertise acquired, risk assessment should also be carried out by doctors (m 9, iqr 2), ambulance personnel (m 9, iqr 3), therapists (m 8.5, iqr 3.75), health care assistants (m 8.5, iqr 3.75) and/or carers.

- 1.3 The timing of risk assessment should be based on each individual case. However, it should take place in under six hours of the start of admission to the episode of care (m 9, iqr 1).

It should be recognised that in some situations – for example acute and critical care – risk assessment should be carried out immediately so as not to delay appropriate preventive measures.

- 1.4 If considered not at risk on initial assessment, reassessment should occur if there is a change in an individual's condition (m 9, iqr 0.25).

Risk assessment should be regarded as a dynamic process. Individuals, regardless of their initial admission status, could become 'at risk' during their contact with the health care system – for example because of a general deterioration in condition or undergoing surgery.

- 1.5 All formal assessments of risk should be documented/recorded (m 9, iqr 0) and made accessible to all members of the inter-disciplinary team (m 9, iqr 0).

Good documentation provides an accurate record of an individual's progress and risk status, and is key for accountability, responsibility, risk management and evaluation.

Strength of Evidence III

These recommendations are based on principles of good practice and the nominal group's clinical experience and opinion.

2.0 Use of risk assessment scales

- 2.1 Risk assessment scales should only be used as an aide memoire and should not replace clinical judgement.

Various scales have been developed to identify individuals at risk of developing pressure ulcers. Most scales have been developed in an ad hoc fashion based on opinions of the relative importance of possible risk factors (EHCB, 1995).

A recently completed systematic review (McGough, 1999) revealed that only the Braden scale has been tested for its predictive validity in comparison to nursing clinical judgement (Salvadalea *et al*, 1992; VandenBosch *et al*, 1996, cited McGough, 1999). These two clinical trials did not demonstrate the scale to be of greater predictive value than clinical judgement.

There is insufficient evidence to recommend one risk assessment scale as unambiguously superior to another, or a scale that is appropriate for use in all care settings (McGough, 1999). As the predictive validity of the six risk assessment scales (Anderson, Braden, Knoll, Norton, Pressure Sore Prediction Scale and Waterlow) is variable, both in comparison with each other and in relation to assessments made of the same scale, on evidence to date it is not possible to make valid comparisons.

Strength of Evidence I

McGough (1999) selected 18 studies which met the criteria for inclusion in her systematic review of the effectiveness of risk assessment tools. Findings from prospective cohort studies led her to conclude risk assessment scales may be useful 'aide memoires' for staff but should not replace clinical judgement (see Appendix 2 for table of included studies). McGough found:

- ◆ 61% of the scales that have been the subject of study are modifications of original scales, where the risk factors included in the original versions have never been questioned
- ◆ 86% of the scales had not been tested for their reliability and validity
- ◆ many of the studies reviewed were of poor quality in respect of methodological rigour, sample sizes and populations, and outcome measurement, resulting in them being susceptible to bias.

2.2 If use of a risk assessment tool is preferred, it is recommended that a scale that has been tested for use in the same specialty is chosen.

If a risk assessment tool is to be used to assist with clinical judgement, McGough suggests that local testing should establish an appropriate cut-off point to indicate risk ('threshold'), that is, the score at which an individual falls into the 'at risk' category.

Strength of Evidence III

This recommendation is based on the opinion of the systematic review author (McGough, 1999).

3.0 Risk factors

3.1 An individual's potential to develop pressure ulcers may be influenced by the following intrinsic risk factors which therefore should be considered when performing a risk assessment:

Reduced mobility or immobility (m 8, iqr 2.5) A key factor in the development of pressure ulcers is reduced mobility or immobility. A number of studies have identified reduced mobility as an independent risk factor in pressure ulcer development.

In a prospective inception cohort study of patients fulfilling certain criteria admitted to a US tertiary university teaching hospital, Allman *et al*, 1995, found that a significant risk factor in patients who went on to develop sores was immobility.

Sensory impairment (m 9, iqr 0) For example neurological disease results in reduced sensation and thus insensitivity to pain or discomfort. This results in a reduced (or lacking) stimulus to move to relieve pressure. There are certain groups of individuals that may suffer from sensory neuropathy, for example those with diabetes and spinal injuries.

Acute illness (m 9, iqr 1) Clinical experience, observation and emerging research suggests that acutely ill patients are vulnerable to developing pressure ulcers. This is because of heart failure, vasomotor failure, vasoconstriction due to shock, pain, low blood pressure (Bliss, 1990) and temperature change – for example during and after anaesthesia (Scott, 2000).

Level of consciousness (m 8, iqr 2) A reduced level of consciousness may reduce an individual's awareness of the need to relieve pressure. Likewise an anaesthetised person has no independence to reposition themselves.

Extremes of age (up to 65, less than 5 years of age) (m 7, iqr 3.25) Advancing age is associated with an increase in cardiovascular and neurological disease, and changes to the resilience and elasticity of the skin. Individuals over 65 years of age are at greater risk than the general population of developing pressure ulcers (Verluisen, 1986; Bergstrom *et al*, 1996; Bergstrom, Braden 1992).

Neonates and very young children are also at a greater risk. Their skin is still maturing and their head-to-body weight is disproportionate. It is currently thought that the factors that place children (m 8, iqr 3) and neonates (m 7, iqr 3.5) at risk are the same that place adults at risk, but the sites of greatest risk for pressure damage and the nature of the injury may differ. For example, there is greater risk of pressure damage to points on the head, on the ears from repeated oxygen saturation measurement, from repeated heel pricks for blood monitoring and an increased risk from extravasation.

Previous history of pressure damage (m 9, iqr 2)

places individuals at a greater risk of developing further ulcers than previously pressure ulcer free patients (Berlowitz and Wilking, 1990; Bergstrom and Braden, 1992; Clark and Watts, 1994).

Vascular disease (m 8.5, iqr 2) reduces total blood flow and impairs micro circulation potentially making patients more vulnerable to pressure necrosis.

Severe chronic or terminal illness (m 8, iqr 2.25)

places individuals at greater risk because of, for example, multi-organ failure, poor perfusion and immobility.

Malnutrition (m 7.5, iqr 3.5) and dehydration

(m 8.5, iqr 2.25), while not directly linked to pressure ulcer development, malnutrition may increase an individual's risk of organ failure and serious illness. Related to this is body weight, both emaciated (Allman *et al*, 1995) and obese individuals may be more vulnerable to pressure damage. Dehydration may reduce the elasticity of tissues and thus increase tissue deformability under pressure or friction (see Essentials of Care section).

- 3.2 The following extrinsic risk factors are involved in tissue damage and should be removed or diminished to prevent injury:

Pressure which causes compression and possible capillary occlusion, which if prolonged can lead to ischaemia. How high the pressure must be and how long it must be exerted to cause damage depends on the individual's tissue tolerance. The key factors are intensity and duration of pressure.

Shearing occurs when the skeleton and deep fascia slide downwards with gravity, whilst the skin and upper fascia remain in the original position. Deep necrosis can occur when the shearing between two layers of tissue leads to stretching, kinking and tearing of vessels in the subcutaneous tissues. Shearing forces should not be considered separately from pressure: they are an integral part of the effect of pressure. Shearing most often occurs when individuals slide down or are dragged up a bed or chair.

Friction occurs when two surfaces move across each other. It often removes superficial layers of skin. Friction damage often occurs as a result of poor lifting techniques (Defloor, 1999).

- 3.3 An individual's potential to develop pressure ulcers may be exacerbated by the following factors which therefore should be considered when performing a risk assessment:

Medication (m 7.5, iqr 2.5) – for example:

- ◆ sedatives and hypnotics may make an individual excessively sleepy and thus reduce mobility
- ◆ analgesics may reduce normal stimulus to relieve pressure
- ◆ inotropes cause peripheral vasoconstriction and tissue hypoxia
- ◆ non-steroidal anti-inflammatory drugs impair inflammatory responses to pressure injury.

This medication list is not exhaustive, practitioners should refer to pharmacists for specialist advice.

Moisture to the skin (m 7, iqr 1.75) – for example urinary and faecal incontinence, wound drainage and sweat (see section on Essentials of Care) are potential irritants to the skin.

Strength of Evidence II

These recommendations have been identified from cohort studies (Bergstrom and Braden, 1992; Papantonio *et al*, 1994; Brandeis *et al*, 1994; Allman *et al*, 1995; Bergstrom *et al*, 1996), the logic and principles of physiology, and are supported by opinion and experience. There is a need for further epidemiological research to improve our understanding of risk factors and the relative contribution they make to the development of pressure ulcers (McGough, 1999).

4.0 Skin inspection

Skin inspection provides essential information for both assessment and prevention. Although the precise role that skin inspection plays in decreasing the incidence of pressure ulcers has not been determined, regular assessment of the most vulnerable parts of the body will enable early detection of incipient pressure damage.

- 4.1 Skin inspection should occur regularly and the frequency determined in response to changes in the individual's condition in relation to both deterioration or recovery (m 9, iqr 0).
- 4.2 Skin inspection should be based on the individualised assessment of the most vulnerable areas of risk and therefore may include different or more areas which require inspection than the examples identified below.
- 4.3 Individuals who are willing and able should be encouraged, following education, to inspect their own skin (m 9, iqr 0).

4.4 Individuals who are wheelchair users should use a mirror to inspect the areas that they cannot see easily (m 9 iqr 0) or get others to inspect them.

4.5 Health care professionals should be vigilant to the following signs which may indicate incipient pressure ulcer development:

- ◆ Heels (m 9, iqr 0)
- ◆ Sacrum (m 9, iqr 0)
- ◆ Ischial tuberosities (m 9, iqr 0)
- ◆ Parts of the body that are affected by the wearing of anti-embolic stockings (m 9, iqr 0)
- ◆ Trochanter (m 9, iqr 0)
- ◆ Parts of the body where pressure, friction or shear is exerted in the course of an individual's daily living activities e.g. on the hands of wheelchair users (m 9, iqr 1)
- ◆ Part of the body where there are external forces exerted by equipment and clothing e.g. endotracheal tubes, intravenous lines, sites of pulse oximetry, catheters, shoes, elastic clothing) (m 9, iqr 1)
- ◆ Elbows (m 7, iqr 1)
- ◆ Temporal region of the skull (m 7, iqr 1.25)
- ◆ Shoulders (m 7, iqr 2.25)
- ◆ Back of head (m 7, iqr 1.75)
- ◆ Toes (m 7, iqr 2.5)

It may not be possible to see the redness/erythema associated with tissue damage in people with darkly pigmented skin. Health care professionals need to be vigilant to the following signs, which may indicate incipient pressure ulcer development in people with darkly pigmented skin (Bennett, 1995):

- ◆ Persistent erythema (m 9, iqr 0.25)
- ◆ *Non-blanching hyperaemia (m 8.5, iqr 2)
- ◆ Blisters (m 8, iqr 3.25)
- ◆ Discolouration (m 7.5, iqr 4)
- ◆ Localised heat (m 7, iqr 2.5)
- ◆ Localised oedema (m 7, iqr 1.5)
- ◆ Localised induration (m 7.5, iqr 2)

4.6 Any skin changes should be documented/recorded immediately (m 9, iqr 0) including a detailed description of what is observed and any action taken.

- ◆ Purplish/bluish localised areas of skin (m 6.5, iqr 4)
- ◆ Localised heat which, if tissue becomes damaged, is replaced by coolness (m 7, iqr 2.25)
- ◆ Localised oedema (m 7, iqr 1.5)
- ◆ Localised induration (m 7.5, iqr 1.5)

Strength of Evidence III

These recommendations are supported by principles of best practice and the nominal group's clinical experience and opinion.

5.0 Pressure redistributing devices

5.1 Decisions about which pressure redistributing device to use should be based on an overall assessment of the individual and not solely on the basis of scores from risk assessment scales.

A recent systematic review (McGough, 1999) concluded that there was insufficient evidence to recommend using risk assessment scale scores on which to base or support decisions about choices of pressure redistributing surfaces. It follows that if risk assessment scales should not be used in isolation to identify individuals at risk, they should not be used in isolation to instigate prevention strategies.

Decisions about support surfaces should be influenced by holistic assessment of an individual's risk (m 9, iqr 4), his/her comfort (m 8, iqr 2.25) and general health state (m 8.5, iqr 1.25). Interface pressure measurements should not be used to make decisions about pressure redistributing devices (m 8.5, iqr 5.25) because they have not been demonstrated to predict reliably the performance of support surfaces (Cullum *et al*, 2000). Assessment should be on-going throughout an individual's episode of care and the type of pressure relief support changed to suit any alteration in risk (m 7, iqr 5.5).

Strength of evidence I

Findings from prospective cohort studies led the reviewer to conclude that staff should not rely solely on risk assessment scale scores (McGough, 1999).

**previously identified as 'non-blanching erythema' – see glossary.*

Strength of evidence III

This recommendation and suggested decision-making practice regarding choice of pressure redistributing devices is also supported by the nominal group's clinical experience and opinion.

5.2 'At risk' individuals should not be placed on standard foam mattresses.

A recently completed systematic review (Cullum *et al*, 2000) concluded that standard foam mattresses have been consistently outperformed by a range of foam-based, low pressure mattresses and overlays, and also by 'higher-tech' pressure redistributing beds and mattresses. The results from four trials comparing foam alternatives with the standard hospital foam mattress (Gray and Campbell, 1994; Hofman, 1994; Santy, 1994 and Collier 1996, cited Cullum *et al*, 2000) were pooled to reveal that various foam alternatives can reduce the incidence of pressure ulcer development in 'at risk' patients. Another randomised, controlled trial (RCT) (Andersen, 1982, cited Cullum *et al*, 2000) comparing alternating pressure surfaces to standard foam mattresses, also reported a reduction in the incidence of pressure ulcers. Cullum *et al*, 2000, note that 'standard' was poorly described in many of the studies included in their review. 'Standard' varies by country, setting and over time.

Other studies comparing alternating pressure devices with a variety of constant low-pressure devices have not shown significant benefits to using one device over another. At present the clearest recommendation is that 'at risk' individuals should be placed on an alternative to the standard foam mattress.

Strength of evidence I

This recommendation is supported by the findings of a systematic review including 29 RCTs of support surfaces for pressure ulcer prevention (Cullum *et al*, 2000).

5.3 Patients at very high risk of developing pressure ulcers should be placed on alternating pressure mattresses or other high-tech pressure redistributing systems.

The EHC (1995) advises that in the absence of clear evidence for an optimal strategy, patients at high risk such as those in intensive care, orthopaedic units or with neurological deficits should be placed on higher-tech surfaces. Cullum *et al*, 2000, report that the relative merits of alternating and constant low pressure, and of different alternating pressure devices are unclear. Many

of the studies which compared devices did not adequately describe the equipment being used, and were small and thus under-powered to detect clinically important differences, even when studies were pooled. There is limited evidence to suggest that low air loss beds (compared to standard ICU beds) reduce the incidence of pressure ulcers in intensive care (Inman, 1993, cited Cullum *et al*, 2000).

Strength of evidence II

Advice from EHC (1995) and one controlled trial.

Individuals undergoing surgery

5.4 Pressure redistributing mattresses/overlays should be used on the operating table of individuals assessed to be at high risk of pressure ulcer development.

Three RCTs have evaluated different methods of pressure relief on the operating table (Nixon *et al*, 1998; Aronovitch, 1998; Dunlop, 1998, cited Cullum *et al*, 2000). Their results suggest that a reduction in post-operative pressure ulcers can be achieved using an alternative support surface to a standard operating table.

The three RCTs evaluated different methods of pressure relief, however, it is currently unclear which type is the most effective (Cullum *et al*, 2000). Nixon *et al*, 1998, found dry visco-elastic polymer pads (Action Products Inc.) to be more effective than a standard table. Whilst Aronovitch, 1998, and Dunlop, 1998, reported in favour of the Micropulse system (an alternating pressure overlay) in comparison to gel pads during surgery and a standard mattress post-operatively.

Some laboratory research has suggested that the 'standard' operating table mattress may be difficult to define and that any pressure redistributing properties are dependent on each product's construction (Scott *et al*, 1999). Individuals that may be at a high risk are those undergoing vascular surgery (m 8, iqr 2.25), orthopaedic surgery (m 9, iqr 3.25), surgery classed as major (m 8.5, iqr 1.5) and those with one of more risk factors (m 7.5, iqr 3.25).

Strength of evidence I

This recommendation is supported by the findings of a systematic review (Cullum *et al*, 2000) including three RCTs that evaluated support surfaces for pressure ulcer prevention on the operating table.

Strength of evidence III

Identified individuals based on the nominal group's clinical experience and opinion.

Post-operative care

- 5.5 To ensure continuity of preventive care, post-operative management of 'at risk' individuals should include the use of pressure redistributing mattresses (m 9, iqr 1.25).

Strength of evidence III

This recommendation for practice is supported by the nominal group's clinical experience.

General issues

- 5.6 Repositioning should occur when individuals are on pressure redistributing devices (m 8.5, iqr 0.25). Frequency of repositioning should be determined by the results of skin inspection (m 9, iqr 1.25), patient comfort (m 8, iqr 1.25) and general state (m 8, iqr 1.25). A change of support surface and/or a change in the frequency of repositioning may be necessary.
- 5.7 The benefits of a pressure redistributing device should not be undermined by prolonged chair sitting (m 8.5, iqr 6.5) (EHCB, 1995)

Strength of evidence III

These recommendations for practice are supported by the nominal group's clinical experience and opinion, and the EHCB (1995).

6.0 Use of aids

- 6.1 The following should not be used as pressure relieving aids:

- ◆ water-filled gloves (m 9 iqr 0)
- ◆ synthetic sheepskins (m 9, iqr 2)
- ◆ genuine sheepskins (m 5, iqr 2.25)
- ◆ doughnut-type devices.

Doughnut-type devices are believed to adversely affect lymphatic drainage and circulation, and thus are likely to cause rather than prevent pressure ulcers (AHCPR, 1992). Water-filled gloves under heels are not effective because the small surface area of the heel means it is not possible to redistribute pressure by this localised method.

Sheepskins do provide comfort to some individuals, but they are not pressure relieving or redistributing aids. If sheepskins are used for comfort rather than perceived pressure relief, care is needed with regard to cross-infection and correct laundering processes.

Strength of Evidence III

This recommendation is based on the nominal group's clinical experience and opinion, AHCPR recommendations (1992 M9 p26) and one trial. Cullum *et al*, 2000, reviewed one small trial of a standard hospital mattress with and without sheepskin overlays (Ewing *et al*, 1964). The trial was of poor quality and the results inconclusive.

7.0 Positioning

- 7.1 Individuals who are 'at risk' of pressure ulcer development should be repositioned (m 9, iqr 0.25).

The frequency of repositioning should be determined by the results of skin inspection and individual needs (m 9, iqr 1.25) not by a ritualistic schedule. This will help to determine and ensure a responsiveness to the time it takes for an individual to show signs of incipient damage.

Repositioning should entail adequate position changes avoiding an individual's vulnerable areas. In cases where individuals have determined their own routine to prevent the development of pressure ulcers, for example those with spinal injury, their knowledge and routine should be respected by health care professionals.

- 7.2 Repositioning should take into consideration other aspects of an individual's condition – for example breathing and medical condition (m 9, iqr 0.25), their comfort (m 9, iqr 1.25), how it fits into their overall plan of care (for example in relation to other activities such as physiotherapy or occupational therapy, meal times, attending to personal hygiene) (m 8, iqr 2.25) and the surface they may be lying or sitting on.
- 7.3 Individuals who are considered to be acutely 'at risk' of developing pressure ulcers should restrict chair sitting to less than two hours (m 8.5, iqr 0.5) until their general condition improves.

- 7.4 Positioning of patients should ensure that:

- ◆ prolonged pressure on bony prominences is minimised (m 8, iqr 1.25)
- ◆ bony prominences are kept from direct contact with one another (m 9, iqr 0.25)

- ◆ friction and shear damage is minimised.
- 7.5 A written/recorded re-positioning schedule agreed with the individual should be established for each person at risk (m 9, iqr 1.25). This record should also include actual position changes.
- 7.6 Individuals/carers who are willing and able should be taught to redistribute their own weight (m 9, iqr 1).
- 7.7 Manual handling devices should be used correctly in order to minimise shear and friction damage. After manoeuvring, slings, sleeves or other parts of the handling equipment should not be left underneath individuals (m 8, iqr 4), as this practice may result in tissue damage. Correct lifting and handling techniques will also reduce the risk to carers' backs.

Strength of Evidence III

These recommendations are supported by the nominal group's clinical experience and opinion and some of the AHCPR (1992) guideline recommendations (M1 p22, M6 p24, M11 p27).

While manual repositioning is an established part of pressure ulcer prevention practice, there is little research demonstrating its effectiveness or the optimal frequency for manual repositioning (EHCB, 1995). However, the nominal group felt that repositioning where appropriate, should form part of pressure relieving practice and should incorporate the principles identified in the above recommendations.

Additionally, a study conducted by Gebhardt and Bliss (1994) compared the outcomes of two groups of elderly orthopaedic patients – one group sat out for unlimited periods and the other sat out for no more than two hours. They found a positive correlation between pressure ulcer development and length of time sitting in a chair.

There is an increasing body of knowledge about the use of the 30 degree lateral tilt (Defloor, 1997; Colin *et al*, 1996). A study of a small sample of healthy volunteers (n=20) found an impairment of oxygen supply to the skin in the 90 degree laterally inclined individuals but not in the 30 degree laterally inclined position (Colin *et al*, 1996).

This is a promising approach to positioning that requires further systematic evaluation before it can be recommended as 'standard' practice. However, it is a lying position that could be used for individuals who find it comfortable.

8.0 Seating

- 8.1 Seating assessments for aids and equipment should be carried out by trained assessors who have the acquired specific knowledge and expertise (for example, physiotherapists/occupational therapists) (m 9, iqr 1.25).
- 8.2 Advice from trained assessors with acquired specific knowledge and expertise should be sought about correct seating positions (m 8, iqr 2).
- 8.3 Positioning of individuals who spend substantial periods of time in a chair or wheelchair should take into account:
 - ◆ distribution of weight (m 9, iqr 1.25)
 - ◆ postural alignment (m 9, iqr 1)
 - ◆ support of feet (m 9, iqr 1).
- 8.4 No seat cushion has been shown to out-perform another, therefore no recommendation can be made about which type to use for pressure redistribution purposes.

Strength of Evidence III

These recommendations are supported by the nominal group's clinical experience and opinion.

Cullum *et al*, 2000, reviewed two RCTs that compared different types of seating cushions. Lim *et al*, 1988, compared a slab with a bespoke contoured foam cushion and found no difference in pressure ulcer incidence. The other trial (Conine *et al*, 1994) compared Jay gel and foam wheel chair cushion with a foam cushion. Although they reported a reduced incidence of pressure ulcer development, this was not found to be statistically significant.

9.0 Education and training

Education of staff and users should be an integral part of any pressure ulcer prevention strategy (Dealey, 1997).

The training and education of users and health care professionals should be tailored to the needs and requirements of the individual and particular professional group. However, there are generic components that should be included in all training programmes.

For all health care professionals

- 9.1 Health care professionals should be trained/educated in pressure ulcer risk assessment and prevention.
- 9.2 Health care professionals with recognised training in pressure ulcer management should cascade their knowledge and skills to their local health care teams (m 9, iqr 0).
- 9.3 An inter-disciplinary approach to the training and education of health care professionals should be adopted (m 9, iqr 0).
- 9.4 Training and education programmes should include the following:
 - ◆ risk factors for pressure ulcer development (m 9, iqr 2.25)
 - ◆ pathophysiology of pressure ulcer development (m 9, iqr 0.5)
 - ◆ the limitations and potential applications of risk assessment tools (m 9, iqr 2.25)
 - ◆ skin assessment (m 9, iqr 0.5)
 - ◆ skin care (m 9, iqr 2.25)
 - ◆ selection of pressure redistributing equipment (m 9, iqr 0.25)
 - ◆ use of pressure redistributing equipment (m 9, iqr 1)
 - ◆ maintenance of pressure redistributing equipment (m 8.5, iqr 1.25)
 - ◆ methods of documenting risk assessments and prevention activities (m 9, iqr 1)
 - ◆ positioning to minimise pressure, shear and friction damage, including the correct use of manual handling devices (m 9, iqr 0.25) (m 8.5, iqr 1)
 - ◆ roles and responsibilities of inter-disciplinary team members in pressure ulcer management (m 9, iqr 1.25)
 - ◆ policies and procedures regarding transferring individuals between care settings (m 9, iqr 1)
 - ◆ patient education and information giving. (m 9, iqr 1)

Strength of Evidence II

Findings from observational studies by Bergstrom *et al*, 1995, and Moody *et al*, 1988, citing McGough systematic

review, 1999, suggest that education programmes may reduce incidence and prevalence of pressure ulcer development. A continuous quality assurance approach would advocate that increasing people's awareness about pressure ulcer risk assessment and prevention, via a co-ordinated and structured educational programme, is more likely to result in benefits for patients than providing no programme, although the effectiveness of educational programmes and what they consist of is currently lacking a reliable research base. These recommendations are supported by AHCPR guideline recommendations (1992, E2:p28), consensus opinion and principles of patient education.

For users and carers

- 9.5 Patients who are able and willing should be informed and educated about risk assessment and resulting prevention strategies. This strategy, where appropriate, should include carers. This information should be tailored to individual requirements. Written information can enhance verbal explanation. The education process should be two way, and patients'/carers' previous knowledge and experience respected.
- 9.6 Patient/carer education should include providing information on the following:
 - ◆ risk factors that are associated with developing pressure ulcers (m 9, iqr 1)
 - ◆ sites that are of the greatest risk of pressure damage (m 9, iqr 1)
 - ◆ how to inspect skin and recognise skin changes (m 9, iqr 0.25)
 - ◆ how to care for skin (m 9, iqr 0.25)
 - ◆ methods for pressure relief/reduction (m 9, iqr 0.25)
 - ◆ where they can seek further advice and assistance should they need it (m 9, iqr 0)
 - ◆ emphasis on the need for immediate visits to a health care professional should signs of skin damage be noticed.

Strength of Evidence III

These recommendations are supported by AHCPR guideline recommendations (E1:p27, 1992), consensus opinion, principles of patient education and one survey which found that individuals who waited longer to go to a clinic presented with more severe pressure damage (Garber *et al*, 1996).

Essentials of care

Nutritional status, continence management and hygiene are essential aspects of care. Their association with pressure ulcer risk assessment and prevention is well documented but not fully understood from the current evidence base, including consensus opinion. Therefore separate recommendations about these issues have not been devised, but in recognition that they are key to raising standards of care (RCN, 1999), this section outlines some principles for practitioners to consider.

Nutritional status

Malnutrition is frequently cited as a risk factor for the presence, development and non-healing of pressure ulcers. Nutritional status influences the integrity of the skin and support structures, and a lack of vitamins and trace elements may predispose the patient to increased risk of pressure damage (Cullum and Clark, 1992). Emaciated and obese people have also been associated with being at a higher risk (Allman *et al*, 1995; Pope, 1999).

However the relationship between nutritional status and pressure ulcers is complex. For example, the poor nutritional status of a person with pressure ulcers may be as much a marker of poor overall health status than as a result of poor nutritional intake. In which case, improving nutritional status *per se* would not improve the outcome for the patient (Finucane, 1995).

Despite a general belief among health care professionals that there is a link between pressure ulcer development and nutritional status, there is currently no research evidence to make this causative association.

Best practice entails monitoring the nutritional status of individuals as part of a holistic assessment procedure and as an ongoing process throughout an individual's episode of care. Initially, this assessment should include documentation and monitoring of the following factors:

- ◆ current weight and height
- ◆ recent weight loss
- ◆ usual eating habits
- ◆ recent changes in eating habits and intake.

If nutritional risk is suspected, practitioners should undertake more detailed screening. A formal nutritional risk assessment scale may be preferred to help with this and nutritionally compromised individuals should be referred to a dietitian.

Continence management

Incontinence is often said to increase the risk of developing pressure ulcers. As with nutritional status, the relationship between incontinence and pressure ulcers is not as obvious as is presumed (Defloor, 1999). Some studies have supported the role of incontinence as a risk factor (Goldstone and Goldstone, 1982) and others have not (Berlowitz and Wilking, 1989).

The key factor is moisture to the skin, which puts it at greater risk from maceration, friction and shearing forces. Therefore the key practice issue is the presence or absence of wet skin (Defloor, 1999). As such, effective management of incontinence is an essential part of skin care and fundamental to maintaining a person's dignity and comfort.

Where the source of moisture cannot be controlled, the use of moisture-absorbing or continence aids could be considered. The use of such aids should not interfere with any pressure redistributing surface an individual may be placed on. Referral to a continence advisor should also be considered on an individual basis.

Hygiene

An individual's skin may be exposed to a variety of moist substances – urine, faeces, perspiration and wound drainage – which may make it more susceptible to injury. The AHCPR (1992) guideline recommends that: skin cleansing should occur at the time of soiling; mild detergents should be used and warm (rather than hot) water to minimise irritation and drying; and moisturisers should be applied to areas of dry skin. Skin rubbing and massage, particularly over bony prominences should be avoided (Dyson, 1978).

Quality improvement

Quality improvement is about constantly looking for ways to do things better (Morrell and Harvey, 1999). It is an iterative process, and requires the commitment of the whole organisation and its stakeholders to work

effectively. Figure 2 offers an example of a quality improvement cycle and related activities for pressure ulcer prevention.

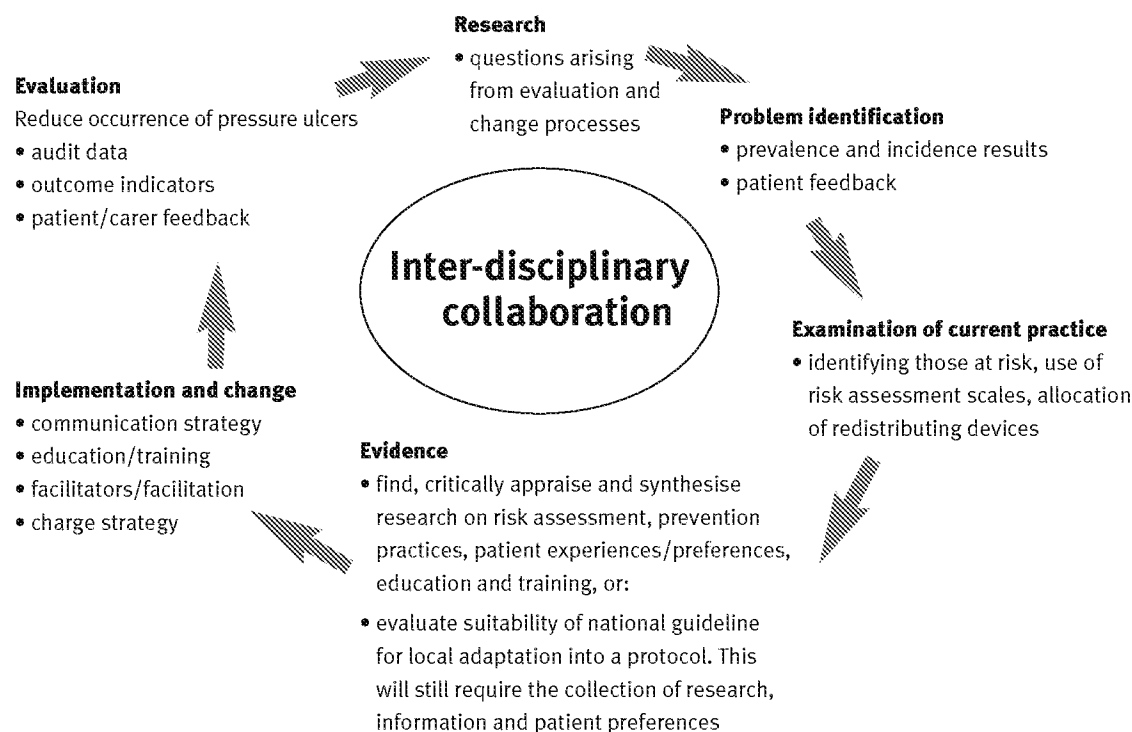


Figure 2. Quality improvement cycle for pressure ulcer prevention – an example

Monitoring pressure ulcers

The presence or absence of pressure sores is often seen as an indicator of quality of care and as such is high on the political agenda (Benchmarking DoH, 2000; Pressure sores: a key quality indicator DoH, 1993; and Health of the Nation, DoH, 1992).

Incidence and prevalence are the two ways to measure pressure ulcer frequency.

Prevalence is the proportion of people with pressure ulcers in a defined period of time. This is affected by, for example, people admitted with existing ulcers, patient healing rates, rates of discharge and successful treatment.

Incidence is the rate at which people initially admitted without an ulcer develop one during a specific period of time. This may be determined by the type of patients admitted (for example those at high risk) and the effectiveness of preventive care.

Comparisons of prevalence between and within care settings are difficult to interpret because they are affected by incidence, healing rates, admission and discharge policies. The measurement of incidence gives a more accurate picture of the success and effectiveness of risk assessment and prevention policies because it identifies those people who have developed ulcers over time and in a particular place of care. Measures of incidence need to be adjusted in the light of the type and number of 'at risk' patients admitted into the particular care settings.

The Benchmarking Fundamental Aspects of Nursing Care project (NHSE, 2000) will also provide a staged approach for practitioners to facilitate the development of practice in pressure area care.

Benchmarks are being developed based on opinion about best practice, with the intention that practitioners use them to score their own current practice and compare this with 'best practice', by sharing examples and networking with others.

Discharge planning

Effective, successful discharge depends on the setting up of care packages based on the needs of the individual. When transferring an 'at risk' patient between care settings and/or to their home, the following factors need to be addressed and communicated:

- ◆ identification of a specific professional who will be responsible for the management of the patient following discharge
- ◆ assessment and indication of level of risk, including date of last assessment – if a risk assessment scale has been used, then the name of the scale should be documented not the score, as scores on one scale mean a different thing on another
- ◆ a description of the condition of the person's pressure areas
- ◆ details of any tissue damage, including size, grade, position and treatment
- ◆ preventive measures the person has required, including the type of pressure re-distributing device(s) used
- ◆ ensuring appropriate measures and equipment are in place prior to transfer or discharge
- ◆ written and verbal information for users/carers about assessment and prevention should be provided.

Audit criteria

Clinical audit should form an integral of organisations' clinical effectiveness activities. The principles and process of clinical audit are well documented (for greater detail see Morrell and Harvey, 1999). It has been defined as:

"...a clinically led initiative which seeks to improve the quality and outcome of patient care through clinicians examining and modifying their practices according to standards of what could be achieved, based on best evidence available or authoritative expert opinion where no objective research-based evidence exists." (Mann, 1996)

Clinical audit should be based on the best available evidence and where national guidelines exist they should be used as a basis for audit activity. The following table provides some evaluative and descriptive statements derived from the recommendations, which could be incorporated into an audit tool.

Those developing measurement tools need to consider and adapt these into structure, process and outcome criteria (see Morrell and Harvey, 1999). Any tools or frameworks developed from the guideline should suit the particular characteristics of the clinical environment and patient caseload(s), and be piloted.

Recommendations

Identifying 'at risk' individuals
Assess and record individuals' level of risk of developing pressure ulcers

Audit criteria

- ◆ Has level of risk been assessed?
On initial contact with the health care system:
- ◆ Has an informal risk assessment on all individuals been conducted?
- ◆ Has a formal assessment of risk been conducted on those people whose initial assessment highlighted factors (triggers) which place them at risk?
- ◆ Has a formal assessment of risk been conducted routinely for in-patients and those visited on domiciliary visits?
- ◆ Is the timing of risk assessment suitable for the patient's condition?
- ◆ In other cases has it taken place in under six hours of admission to the episode of care?
- ◆ Are the results of the assessment recorded/documented?
- ◆ Is an individual's level of risk accessible to all members of the inter-disciplinary team?
- ◆ Does reassessment of risk occur when an individual's condition alters?

How to audit

Documentation/recording of process and results of risk assessment: time, date, personnel. If individual's condition alters, is there a record of reassessment?
Is the documentation/records held in a place accessible to all members of the inter-disciplinary team?

Who carries out risk assessment	<ul style="list-style-type: none"> ◆ Has a suitably trained member of staff carried out the risk assessment(s)? 	<p>Documentation/records to identify personnel carrying out risk assessment.</p> <p>Records of training and education/induction programmes reflect attendees carrying out risk assessment.</p>
Risk assessment scales	<ul style="list-style-type: none"> ◆ How has risk assessment been performed? <ul style="list-style-type: none"> – Is there evidence that clinical judgement has also been involved in risk assessment activities? – If a risk assessment tool is used – is it appropriate to the clinical speciality in which it is being used? 	<p>Documentation/recording of risk –</p> <ul style="list-style-type: none"> – name of the scale? – evidence of scores? – evidence of consideration of broader issues/risk factors (intrinsic/extrinsic/exacerbating)? <p>Ask health care personnel how level of risk has been assessed</p>
Skin inspection	<ul style="list-style-type: none"> ◆ Does skin inspection occur regularly and frequently in response to changes in an individual's condition? ◆ Does skin inspection focus on areas of known vulnerability and also on areas of the body that are susceptible based on individualised assessment? ◆ Are changes documented immediately? 	<p>Documentation/records show times, dates and results of skin inspection. Also documentation/records of action taken.</p> <p>Observation of practice.</p> <p>Ask health care professionals how skin inspection is performed and what signs they look out for.</p> <p>Ask patients if their skin was inspected.</p>
Pressure redistributing devices	<ul style="list-style-type: none"> ◆ Is the choice of pressure redistributing device based on an overall assessment of the individual? ◆ What other factors were taken into account? ◆ Are individuals assessed to be 'at risk' on an alternative to a standard mattress? ◆ Are individuals assessed to be at high risk on an alternating pressure mattress or other high-tech device? ◆ Are support surfaces changed to meet alterations in an individual's condition? ◆ Are individuals at high risk placed on pressure redistributing overlays during surgical procedures? ◆ Does post-operative care for these individuals include similar support surfaces? ◆ Are individuals repositioned whilst on pressure redistributing devices? 	<p>Documentation/records to include decision trail and factors taken into account when making decisions about support surfaces, including documentation/recording of any organisational constraints.</p> <p>Accurate recording of what support surfaces individuals are on (e.g. care plans, records of hiring or equipment library records).</p> <p>Mattress and support surface audits.</p>
Aids	<ul style="list-style-type: none"> ◆ Is there any evidence to suggest that inappropriate aids such as: <ul style="list-style-type: none"> – water-filled gloves – synthetic/genuine sheepskins – donut type devices are being used? 	<p>Documentation/records and observation of practice.</p>

Repositioning	<ul style="list-style-type: none"> ◆ Is there evidence that individuals assessed to be 'at risk' are being repositioned? ◆ Are repositioning schedules being tailored to individual needs and results of skin inspection? ◆ Do individuals have written repositioning schedules? ◆ Are correct lifting and handling procedures being adhered to? ◆ Is repositioning avoiding pressure on bony prominences? 	<p>Documentation/records to reflect individualised repositioning schedules.</p> <p>Observation of practice.</p> <p>Ask users about their involvement in care.</p>
Seating	<ul style="list-style-type: none"> ◆ Are seating assessments carried out by appropriately trained assessors? ◆ Does positioning take into account: <ul style="list-style-type: none"> – distribution of weight – postural alignment – support of feet? ◆ Is chair sitting limited to a maximum of two hours for those at risk of developing pressure ulcers? 	<p>Documentation/records to reflect advice and assessment by appropriate assessors?</p> <p>Asking staff about their practice.</p> <p>Observation of practice.</p>
Education and training – health care professionals	<ul style="list-style-type: none"> ◆ Are health care professionals trained in pressure ulcer risk assessment and prevention? ◆ What is included in this training? ◆ How is competence assessed? ◆ How is competence maintained/knowledge updated? 	<p>Induction/training and education records.</p> <p>Ask trainers.</p> <p>Ask health professionals about their training.</p>
– users	<ul style="list-style-type: none"> ◆ Are users a) informed and b) educated about a) pressure ulcer risk assessment and b) prevention strategies? ◆ What does this education include? ◆ How has understanding been assessed ? 	<p>Ask users if they have received a) information and b) education. What did this entail?</p> <p>Ask health care professionals about what information and education they gave users.</p>

Glossary

Alternating pressure device: device that mechanically varies the pressure beneath the individual thus reducing the duration of applied pressure.

Bias: the deviation of results from 'the truth', due to systematic error(s) in the methods used.

Cellulitis: a spreading infection of connective tissue, especially subcutaneous tissue.

Cochrane Collaboration: an international organisation in which people retrieve, appraise and review available randomised controlled trials. The Cochrane Database of systematic reviews contains regularly updated reviews on a variety of issues. The Cochrane Library is the database for the collaboration, it is electronic and regularly updated.

Constant low pressure devices: devices that mould around the shape of the patient to distribute weight over a large area

Critical appraisal: the process of assessing the validity, results and relevance of evidence, often in conjunction with a structured framework/tool.

Effectiveness: the extent to which an intervention does more good than harm.

Erythema: non-specific redness of the skin which can either be localised or general in nature and which may be associated with cellulitis, infection, prolonged pressure or reactive hyperaemia. *See Collier 1999b for more details.*

- **Reactive hyperaemia:** the characteristic bright flush of the skin associated with an increased volume of the pulse on the release of an obstruction to the circulation, or a vascular flush following the release of an occlusion of the circulation which is a direct response to incoming arterial blood.
- **Blanching hyperaemia:** is the distinct erythema caused by reactive hyperaemia, when the skin blanches or whitens if light finger pressure is applied, indicating that the patient's micro-circulation is intact.
- **Non-blanching hyperaemia** (previously identified as non-blanching erythema): is indicated when there is no skin colour change of the erythema when light finger pressure is applied, indicating a degree of microcirculatory disruption often associated with other clinical signs, such as blistering, induration and oedema.

Extrinsic: not belonging, lying outside, in the case of pressure ulcer development, factors that are external to the individual

Incipient: initial stages, beginning to exist.

Induration: the abnormal hardening of tissue (or organ).

Intrinsic: inherent, thus in the case of pressure ulcer development, factors present within the individual.

Maceration: a softening or sogginess of the tissue caused by the retention of excessive moisture.

Necrosis: the local death of tissue, often black/brown in colour and leathery in texture.

Oedema: increase in fluid in inter-cellular space, swelling.

Overlay: term used to describe surfaces placed on top of a standard mattress or operating table.

Predictive validity: a risk assessment tool would have high predictive validity if the predictions it makes of pressure sore development in a sample largely became true i.e. it has both high sensitivity and high specificity.

RCT: randomised controlled trial – a trial in which subjects are randomly assigned to either a group receiving an intervention that is being tested or another group receiving an alternative or no intervention. The results compare the outcomes of the different groups.

Search strategy: the method used for searching for articles to answer particular questions.

Sensitivity: what percentage of those who developed pressure ulcers in the study were predicted to be at risk by the score.

Specificity: what percentage of participants were correctly predicted to be not at risk by the score (a specificity of 100% means that all the participants who did not develop ulcers had been predicted to be not at risk).

Systematic review: a review in which evidence on a topic has been systematically identified, appraised and summarised according to pre-determined criteria.

Validity: a study is valid if the way it is designed and carried out means that the results are unbiased.

30 degree lateral tilt: the patient is placed in the laterally inclined position, supported by pillows, with their back making a 30 degree angle with the support surface.

95% confidence intervals: while a study will give single values of sensitivity and specificity for a risk score, these are based on the experience of the handful of people in the study and are the best guesses as to what would happen if the study was to be repeated. Where sample sizes are small, there will be high imprecision in the estimates of sensitivity and specificity.

Sources: Collier ME, 1999b; Harding K, 2000; Baillière's Nurses Dictionary, 1997; Cullum *et al*, 2000; Heinemann Medical Dictionary, 1986.

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Appendix 1

Outline of consensus method

For full details of the guideline method refer to the *Technical Report* (Rycroft-Malone and McInness, 2001).

Figure 3 (right) summarises the consensus development process.

The formal consensus development process was based on a modified nominal group technique (see *Technical Report* for rationale and full details). Ten people, who reflected the full range of those to whom the guideline will apply, were recruited to the nominal group (see group membership in Appendix 5). Prior to a meeting, participants were asked to rate statements that had been devised from the AHCPR guideline recommendations, systematic reviews, other literature and current practice issues. They were asked to rate on a 1– 9 scale (where 1 represented least agreement and 9 most agreement) their agreement with these statements taking into account the research evidence and their clinical expertise. The first rating was conducted by post.

The nominal group met in November 1999. The distribution of responses to each statement was presented to group members during the consensus meeting alongside each member's response to that statement. This enabled participants to see the spread of views and how their response related to this.

At the nominal group meeting each statement was discussed and then re-rated privately by each participant. The median (measurement of central tendency or average) and inter-quartile range (measure of distribution) was calculated for each statement from the ratings of the second round.

The recommendations were drafted based on the panel's level of agreement about issues. If a statement's median was 7 – 9, it was developed into a practice recommendation.

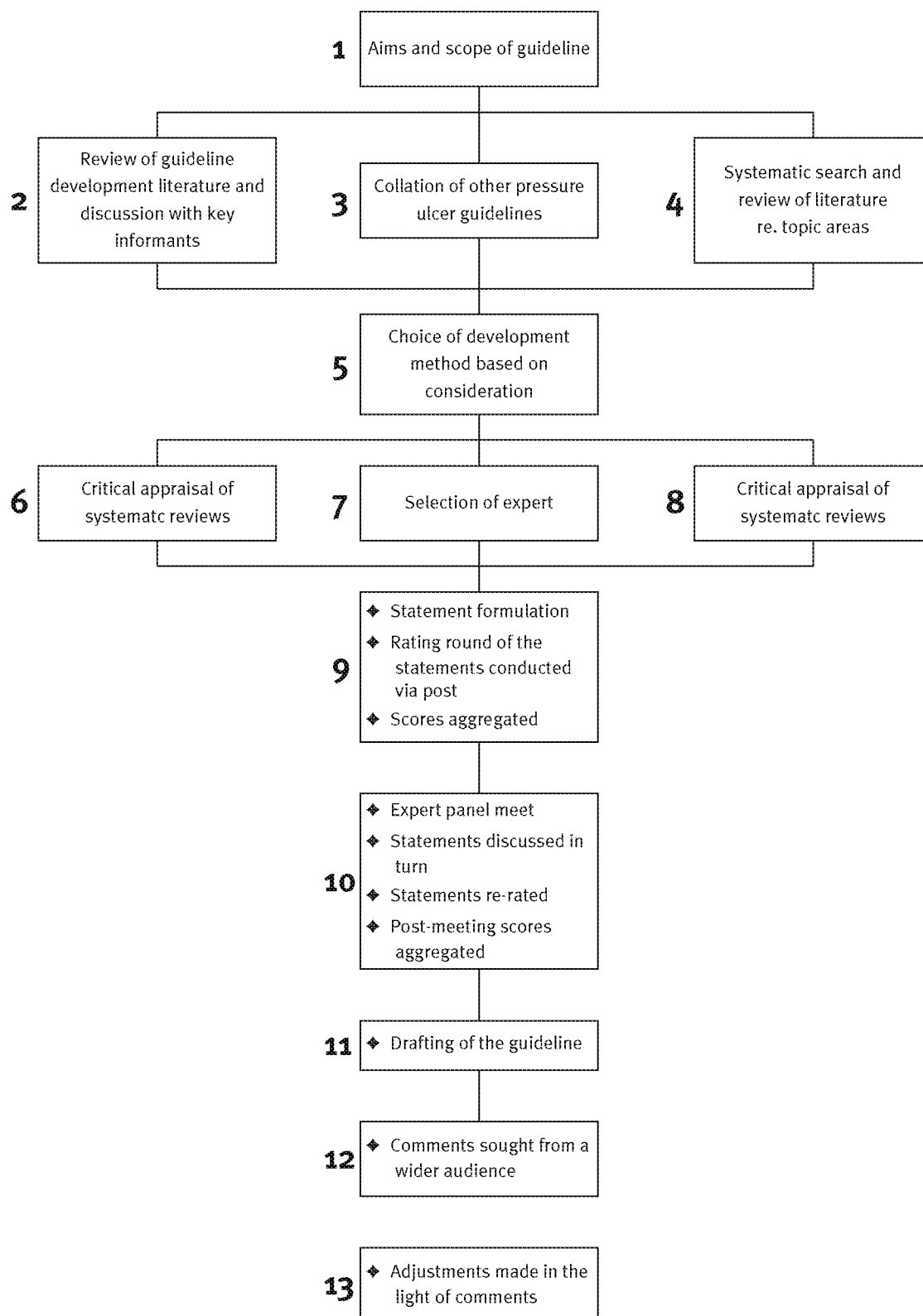


Figure 3. Consensus process for guidelines – summary

Appendix 2

McGough Systematic Review (1999)

See Technical Report for table of excluded studies. Studies included in review

Authors	Title	Reference
Andersen scale		
Andersen KE, Jensen O, Kvorning SA and Bach E	Prevention of pressure sores by identifying patients at risk	British Medical Journal 1982 284: 1370-1
Braden scale		
Barnes D and Payton RG	Clinical application of the Braden scale in the acute care setting	Dermatology Nursing 1993 5 (5): 386-88
Bergstrom N and Braden B	Prospective study of pressure sore risk among institutionalised elderly	Journal of American Geriatric Society 1992 40 (8): 747-58
Bergstrom N, Braden BJ, Laguzza A and Holman V	The Braden scale for predicting pressure sore risk	Nursing Research July/August 1987 36 (4): 205-10
Bergstrom N, Demuth PJ and Braden BJ	A clinical trial of the Braden scale for predicting pressure sore risk	Nursing Clinics of North America June 1987 22 (2): 417-28
Braden BJ and Bergstrom N	Predictive validity of the Braden scale for pressure sore risk in a nursing home population	Research in Nursing and Health 1994 17: 459-70
Capobianco ML and McDonald DD	Factors affecting the predictive validity of the Braden scale	Advances in Wound Care 1996 9 (6): 32-6
Halfens RJ	The reliability and validity of the Braden scale	Proceedings of the 1st European Pressure Ulcer Advisory Panel 1997
Langemo DK, Olson B, Hunter S, Hanson D, Burd, C and Cathcart-Silberberg T	Incidence and prediction of pressure ulcers in five patient care settings	Decubitus 1991 4 (3): 25-36
Ramundo JM	Reliability and validity of the Braden scale in the home care setting	Journal of Wound Ostomy and Continence Nursing 1995 22 (3): 128-34
Salvadalena G, Snyder ML and Brogdon KE	Clinical trial of the Braden scale on an acute care medical unit	Journal of Enterostomal Therapy 1992 19: 160-65
VandenBosch T, Montoye C, Satwicz M, Durkee-Leonard K and Boylan-Lewis B	Predictive validity of the Braden scale and nurse perception in identifying pressure ulcer risk	Applied Nursing Research 1996 May 9 (2): 80-86
Knoll scale		
Towey AP and Erland SM	Validity and reliability of an assessment tool for pressure ulcer risk	Decubitus 1988 1 (2): 40-48

Norton scale

Norton D, McLaren R, Exton-Smith AN

An investigation of geriatric nursing problems in hospital

The National Corporation for the Care of Old People London 1962

Stotts NA

Predicting pressure ulcer development in surgical patients

Heart and Lung 1988 17 (6) 1: 641-47

Pressure Sore Prediction Score

Lowthian P

Identifying and protecting patients who may get pressure sores

Nursing Standard 1989 4 (4) : 26-29

Waterlow scale

Edwards M

The levels of reliability and validity of the Waterlow Pressure Sore Risk Calculator

Journal of Wound Care 1995 4 (8): 373-378

Waterlow and Norton scales

Wai-Han C, Kit-Wai C, French P, Yim-Sheung L and Lai-Kwan T

Which pressure sore risk calculator? A study of the effectiveness of the Norton scale in Hong Kong

International Journal of Nursing Studies 1997 34 (2): 165-9

Appendix 3

Cullum et al (2000) Systematic Review

See Technical Report for table of excluded studies. Studies included in review

Authors

Allman RM, Walker JM, Hart MK, Laprade CA, Noel LB, and Smith CR

Title

Air-fluidized beds or conventional therapy for pressure sores – a randomised trial

Reference

Annals of Internal Medicine 1987 107(5): 641-648

Andersen KE, Jensen O, Kvorning SA and Bach E

Decubitus prophylaxis: a prospective trial on the efficiency of alternating pressure air mattresses and water mattresses

Acta Dermatovener (Stockholm) 1982 63: 227-230

Aronovitch SA

A comparative, randomized, controlled study to determine safety and efficacy of preventive pressure ulcer systems; preliminary analysis

Acquired Pressure Ulcers, Advances in Wound Care (Supplement) 1998

Caley L, Jones S, Freer J

Randomised prospective trial of two types of low air loss therapy

Unpublished conference paper

Clark M and Donald IP

A randomised controlled trial comparing the healing of pressure sores upon two pressure-redistributing seat cushions

Proceedings of the 7th European Conference on Advances in Wound Management, Harrogate 1999 London: Macmillan Magazines

Collier ME

Pressure-reducing mattresses

Journal of Wound Care 1996 5(5): 207-211

Conine TA, Daechsel D and Lau MS

The role of alternating air and silicone overlays in preventing decubitus ulcers

Journal of Rehabilitative Research 1990 13: 57-65

Conine TA, Hershler C, Daechsel D, Peel C, and Pearson A	A pressure sore prophylaxis in elderly patients using polyurethane foam or Jay wheelchair cushions	International Journal of Rehabilitative Research 1994 17: 123-137
Cooper PJ, Gray DG and Mollison J	A randomised controlled trial of two pressure reducing surfaces	Journal of Wound Care 1998 7(8): 374-376
Daechsel D and Conine TA,	Special mattresses: effectiveness in preventing decubitus ulcers in chronic neurological patients	Archives of Physical Medicine and Rehabilitation 1985 66: 246-248
Devine B	Alternating pressure air mattresses in the management of established pressure sores	Journal of Tissue Viability 1995 5: 94-98
Dunlop V (1998) (Micropulse Inc. reference in original review)	Preliminary results of a randomised, controlled study of a pressure ulcer prevention system	Acquired Pressure Ulcers, Advances in Wound Care (Supplement)
Economides NG, Skoutakis VA, Carter CA and Smith VH	Evaluation of the effectiveness of two support surfaces following myocutaneous flap surgery	Advances in Wound Care 1995 8:49-53
Ewing MR, Garrow C, Presley TA, Ashley C and Kinsella NM	Further experiences in the use of sheep skins as an aid in nursing	The Australian Nurses' Journal 1964 Sept 215-219
Exton-Smith AN, Overstall PW, Wedgewood J and Wallace G	Use of 'air wave system' to prevent pressure sores in hospital	Lancet 1982 ii:1288-1290
Ferrell BA, Osterweil D and Christenson P	A randomised controlled trial of low air loss beds for treatment of pressure ulcers	JAMA 1993 269: 494-497
Gebhardt K	A randomised trial of alternating pressure (AP) and constant low pressure (CLP) supports for the prevention of pressure sores	Journal of Tissue Viability 1994 4(3):93
Gentilello L, Thompson DA, Tonnesen AS, Hernandez D, Kapadia AS, Allen SJ, Houtchens BA and Miner ME	Effect of rotating bed on the incidence of pulmonary complications in critically ill patients	Critical Care Medicine 1988 16: 783-786
Goldstone L, Norris M, O'Reilly M, White J	A clinical trial of a bead bed system for the prevention of pressure sores in elderly orthopaedic patients	Journal of Advanced Nursing 1982 7: 545-548
Gray DG and Campbell M	A randomised clinical trial of two types of foam mattresses	Journal of Tissue Viability 1994 4: 128-132
Hampton S	Evaluation of new Cairwave Therapy System in one hospital trust	British Journal of Nursing 1997: 6(3): 167-170
Hofman A, Geelkerken RH Hamming JJ	Pressure sores and pressure-decreasing mattresses: controlled clinical trial	Lancet 1994 343: 568-571
Inman KJ Sibbald WJ and Rutledge FS	Clinical utility and cost-effectiveness of an air suspension bed in prevention of pressure ulcers	Journal of the American Medical Association 1993 269: 1139-1143

Kemp MG, Kopanke D, Tordecilla L <i>et al</i>	The role of support surfaces and patient attributes in preventing pressure ulcers in elderly patients	Research in Nursing and Health 1993 16: 89-96
Laurent S	Effectiveness of pressure decreasing mattresses in cardiovascular surgery patients: a controlled clinical trial	3rd European Conference for Nurse Managers Brussels October 1997
Lazzara DJ, Buschmann MBT	Prevention of pressure ulcers in elderly nursing home residents: are special support surfaces the answer?	Decubitus 1991 4: 42-26
Limm R, Sirett R, Conine TA <i>et al</i>	Clinical trial of foam cushions in the prevention of decubitus ulcers in elderly patients	Journal of Rehabilitation Research 1988 25: 19-26
Munro BH, Brown L, Heitman BB	Pressure ulcers: one bed or another?	Geriatric Nursing 1989 10: 190-2
Nixon J, McElvenny D, Mason S, Brown J, Bond S	A sequential randomised controlled trial comparing a dry visco-elastic polymer pad and standard operating table mattress in the prevention of postoperative pressure sores	International Journal of Nursing Studies 1998 35: 1932-3
Santy JE, Butler MK, Whyman JD	A comparison study of six types of hospital mattresses to determine which most effectively reduces the incidence of pressure sores in elderly patients with hip fractures in a District General Hospital	Report to Northern & Yorkshire Regional Health Authority 1994
Sideranko S, Quinn A, Burns K, Froman RD	Effects of position and mattress overlay on sacral and heel pressures in a clinical population	Research in Nursing & Health 1992: 15: 245-251
Stapleton M	Preventing pressure sores – an evaluation of three products	Geriatric Nursing 1986 6: 23-25
Strauss MJ, Gong J, Gary BD, <i>et al</i>	The cost of home air-fluidized therapy for pressure sores A randomised controlled trial	Journal of Family Practice 1991 33: 52-59
Summer WR, Curry P, Haponikm EF, Nelson S, Elston R	Continuous mechanical turning of intensive care unit patients shortens length of stay in some diagnostic-related groups	Journal of Critical Care 1989 4: 45-53
Takala J, Varmavuo S, Soppi E	Prevention of pressure sores in acute respiratory failure: a randomised controlled trial	Clinical Intensive Care 1996 7: 228-235
Vyhlidal SK, Moxness D, Bosak KS, Van Meter FG, Bergstrom N	Mattress replacement or foam overlay: a prospective study on the incidence of pressure ulcers	Allied Nursing Research 1997 10 (3): 111-20
Whitney JD, Fellows BJ, Larson E	Do mattresses make a difference?	Journal of Gerontological Nursing 1984 10:20-25

Appendix 4

Studies included in update of AHCPR review

See Technical Report for table of excluded studies

Study	Design including sampling strategy	Results	Comments	Conclusions
<p>Finucane (1995)</p> <p>To review data about the relationship between pressure sores and 1) nutritional status 2) nutrient intake and 3) tube feeding</p>	<p>Literature review</p>	<p>(findings in relation to pressure ulcer development)</p> <p>Low serum albumin associated with the development or presence of sores in seven studies, in five others it was not</p> <p>Most measures of nutritional status were not associated with pressure sore outcomes</p> <p>Poor nutritional intake associated with poor pressure sore outcome in four out of seven studies</p>	<p>Not all available data captured</p>	<p>Data on relationship between malnutrition and pressure ulcers is incomplete and contradictory</p> <p>There is no real evidence that there is any association between malnutrition and development of pressure ulcers</p> <p>No evidence to suggest that correcting malnutrition reduces the likelihood of developing pressure ulcers</p>
<p>Garber <i>et al</i> (1996)</p>	<p>Survey via interviews assessing demographic, Spinal Chord Injury (SCI) and ulcer characteristics, detection method, immediacy and appropriateness of action, time from detection to clinic visits, number of prior ulcers and knowledge and practice of ulcer prevention techniques</p> <p>Sampling: convenience</p> <p>Setting: patients presenting at a community based outpatient plastic surgery clinic</p> <p>N= 23 (20 men, 3 women), with ulcers that were of 12 weeks' duration or less</p>	<p>Individuals who waited longer to go to the clinic presented with more severe ulcers</p>	<p>Small sample size</p>	<p>Education programmes should emphasise immediate visits to the physician on detection of an ulcer</p> <p>Individuals with SCI should be encouraged to have another person inspect their skin regularly – even if they are capable of doing it themselves</p>

Study	Design including sampling strategy	Results	Comments	Conclusions
<p>Brandeis <i>et al</i> (1994)</p> <p>To determine risk factors associated with the formation of stage II-IV pressure ulcers in nursing homes</p>	<p>Longitudinal cohort study</p> <p>4,232 nursing home residents in 78 homes, over 60 years of age, 73% women, admitted without pressure ulcers</p> <p>Homes divided up based on incident rates of pressure ulcer formation – high and low incidence homes</p> <p>Assessed at 3, 6 and 21 months for presence of pressure ulcers</p> <p>Data collected on variables such as age, gender, antipsychotic medications, Body Mass Index cognitive status, incontinence, mobility, and an Activity of Daily Living score</p> <p>Pooled logistic regression</p>	<p>In high incidence homes – faecal incontinence, difficulty with mobility, diabetes and difficulty feeding oneself were significant independent factors</p> <p>In low incidence homes – difficulty with mobility, difficulty feeding oneself and male sex were significant independent factors</p>	<p>The nursing homes themselves may play a greater role in pressure ulcer development than the characteristics of the residents because practice was not controlled for</p> <p>Not all potential risk factors were investigated</p> <p>Nursing home staff carried out measures with only intermittent checks on reliability</p>	<p>By identifying and controlling for specific risk factors within certain populations pressure, ulcer incidence may be reduced</p>
<p>Papantonio <i>et al</i> (1994)</p> <p>To examine the incidence and risk factors related to the development of sacral pressure ulcers following elective surgery</p>	<p>Cohort study</p> <p>Convenience sample of 136 adult patients (66% male) undergoing elective surgery</p> <p>Measurement of pre-, intra-, and post-operative variables, such as demographics, BMI, pre-existing medical conditions, position on table, use of thermal under blankets, and skin condition</p> <p>6 day follow up period</p>	<p>Variables such as diabetes, increasing age, transfer from another hospital, respiratory disease and haematocrit levels were found to be associated with pressure ulcer development</p>	<p>Assessments carried out by a number of different assessors</p> <p>No strict inclusion criteria of patients</p> <p>Size of ulcer not recorded and collapsed stage I and II damage may have overestimated damage</p> <p>Limited to cardiac surgery</p>	<p>People judged prior to surgery as being 'healthy' are at risk of developing pressure ulcers during cardiac surgery</p>

Study	Design including sampling strategy	Results	Comments	Conclusions
<p>Bergstrom and Braden (1992)</p> <p>To determine if dietary intake, nutritional status, and other physical markers are risk factors for the development of pressure ulcers in the elderly</p>	<p>Cohort study</p> <p>200 newly admitted patients, 70% female, over 65 years of age, to a 250 bedded nursing home</p> <p>Skin assessment, Braden Scale score, blood pressure, temperature, anthropometric measurements and dietary intake were studied weekly</p> <p>Serum zinc, albumin, iron, copper and vitamin C were studied weekly for 4 weeks and biweekly for 8 weeks</p> <p>Main outcome measure – the presence or absence of pressure ulcers</p>	<p>Stage I pressure ulcers developed in 35% and stage II or worse in 38.5% of residents</p> <p>Age, blood pressure, temperature, dietary protein, iron and Braden score emerged as significant predictors of pressure ulcer development in logistic regression analysis</p>	<p>Background of patients unclear in relation to UK populations</p> <p>Selection bias present</p> <p>Results should be interpreted in the light of the pressure ulcer prevention practices of the nursing home in which the study took place</p>	<p>These are factors that practitioners need to be aware that may increase a person's risk of developing pressure ulcers</p> <p>A formal, structured risk assessment should be undertaken on people admitted to nursing homes</p>

improving practice:
improving care

CLINICAL PRACTICE GUIDELINES

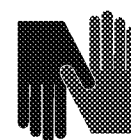
Published by the Royal College of Nursing
20 Cavendish Square, London, W1G 0RN

Telephone 020 7409 3333

April 2001

ISBN 1-873853-74-2

Publication code 001 252



Royal College
of Nursing

EXHIBIT C

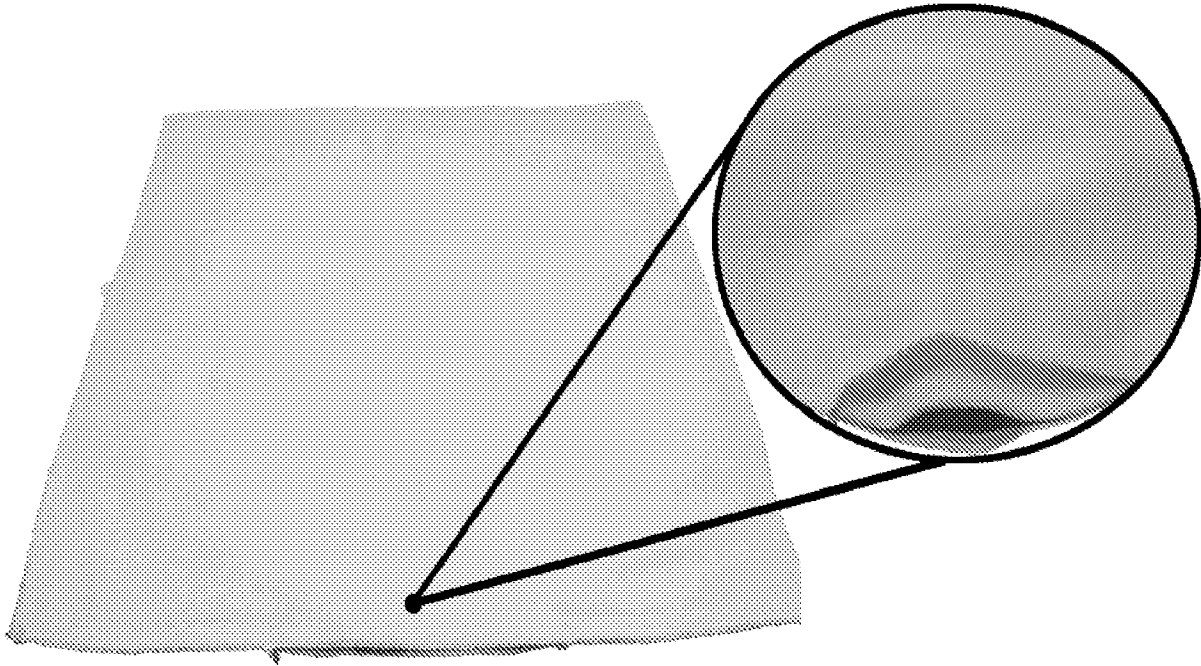
FROM PAST TO PRESENT . . .
TO FUTURE:

THE STORY OF PATIENT UNDERPADS

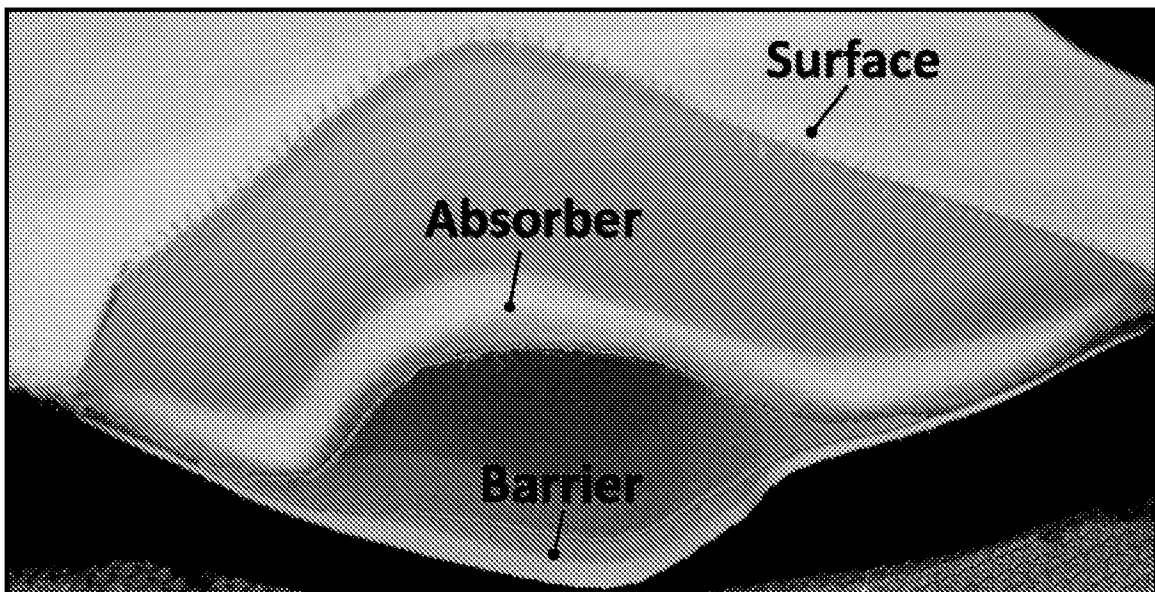
By **MIP** 

THE PAST...

In the beginning, patient underpads were not quilted



Patient underpads had 3 layers:
The Surface, the Absorber and the Barrier



...Unquilted Patient Underpads allowed for lots of movement between the 3 seperate layers, which caused pilling and created bunching (as displayed below)

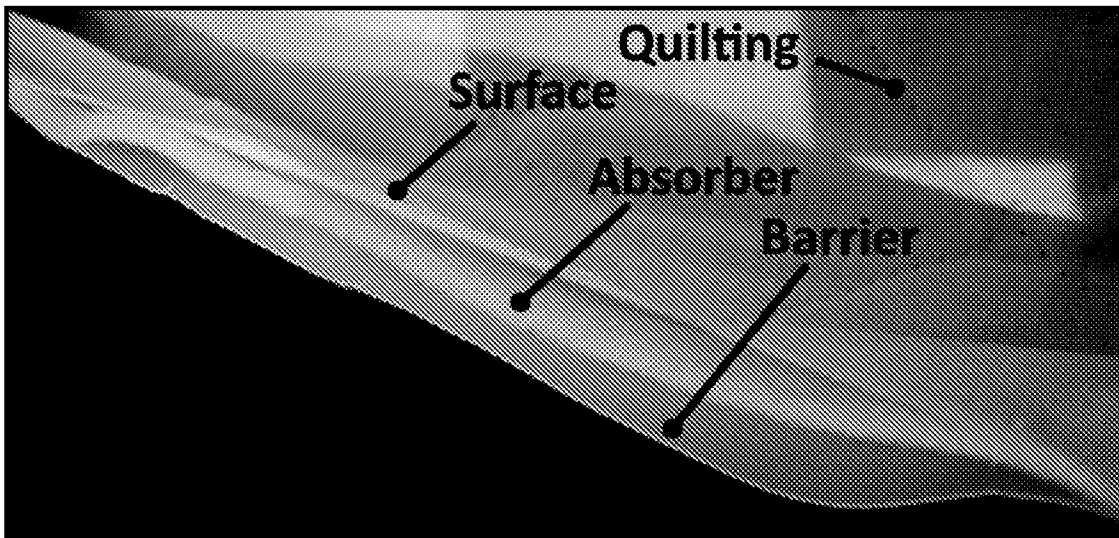


And the story continues...

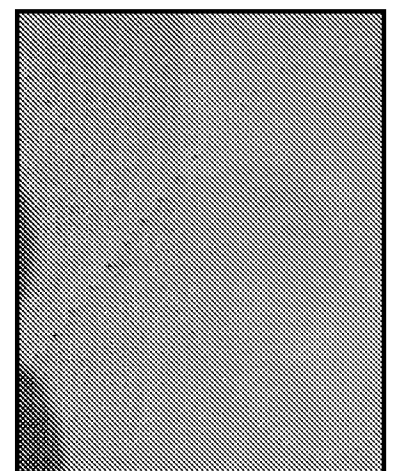
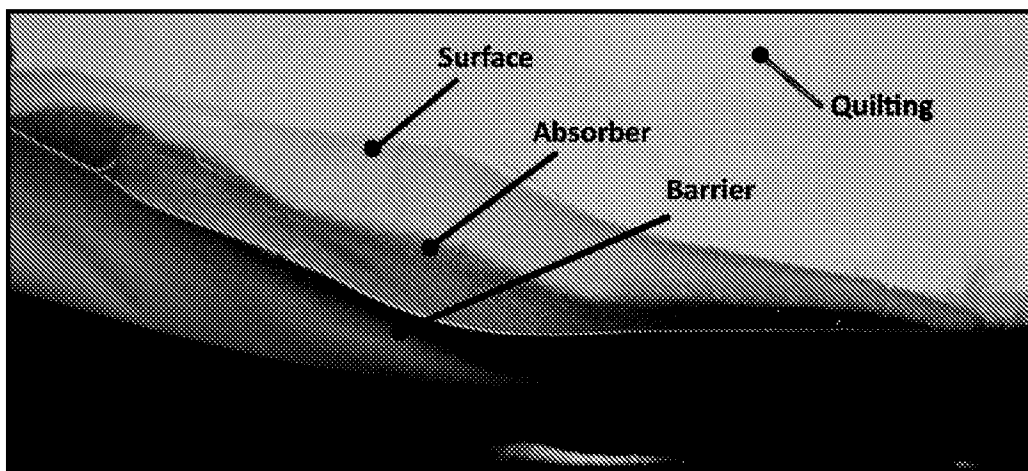
THE PRESENT . . .

Then, Patient Underpads were modified by quilting the Surface and the Absorber together. This procedure eliminated some movement between the layers (Surface & Absorber), but movement between the Barrier and the Absorber still remained

Example 1:



Example 2:



Quilting

THE PRESENT . . .

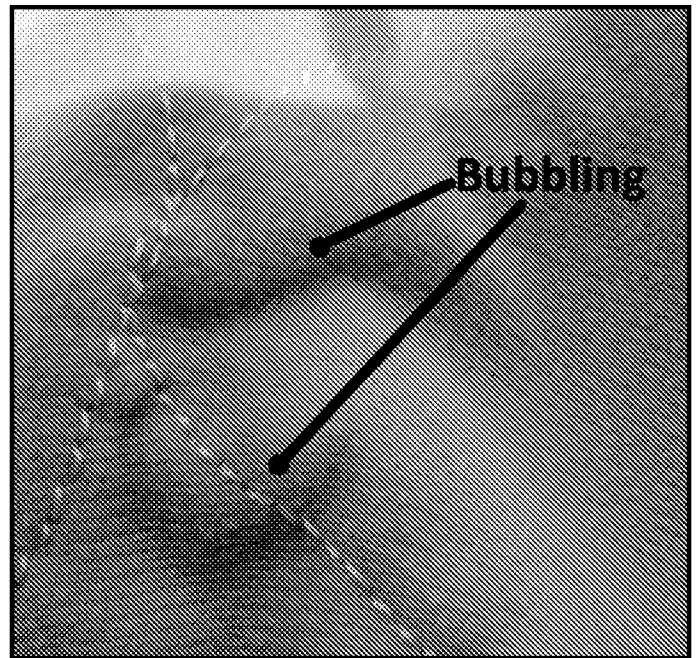
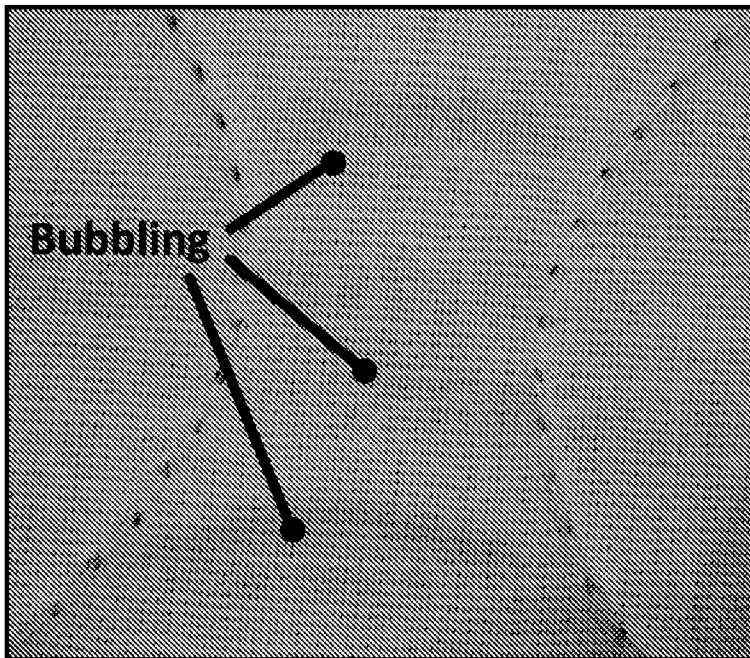
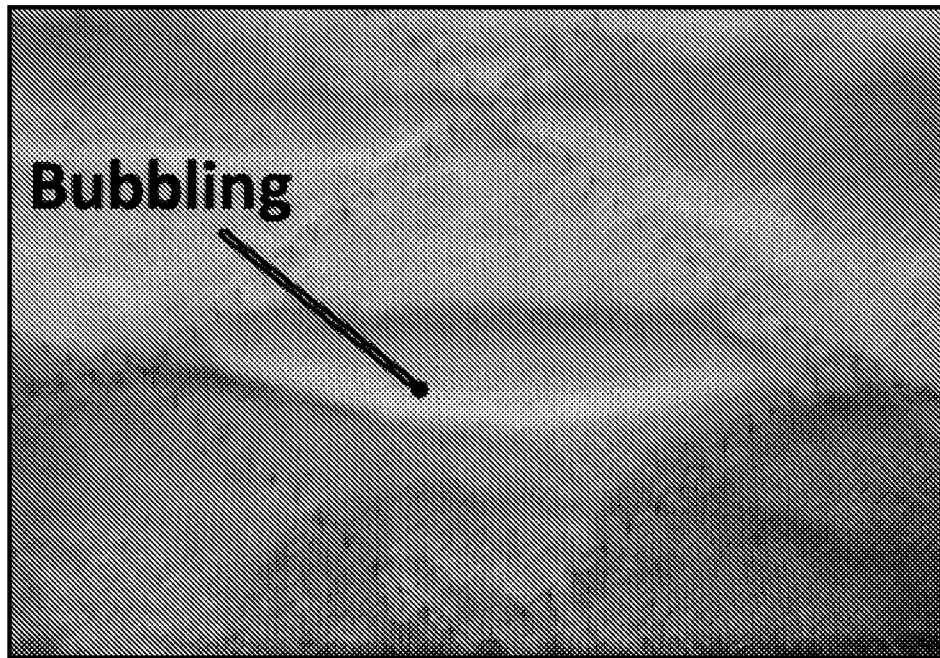
By quilting the Surface and the Absorber together, washing the pads caused shrinkage that was not consistent between the two layers and rendered the pad less esthetically appealing and reduced patient comfort. (Examples below)

It created uneven "Shrinkage":



THE PRESENT...

This caused a "Bubbling" effect:

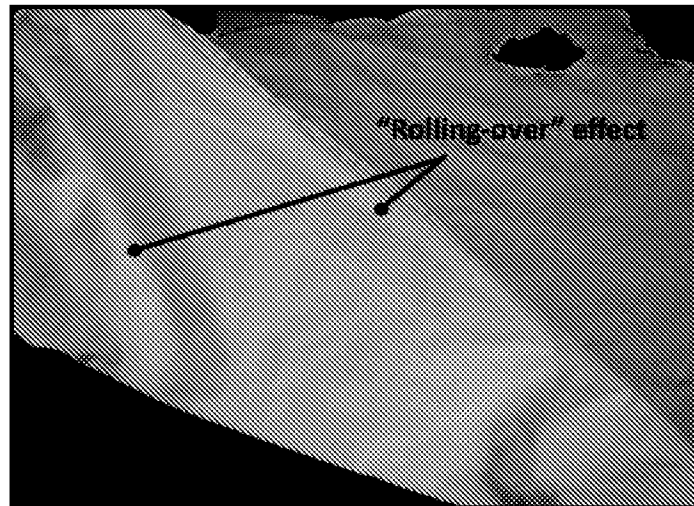


...Furthermore

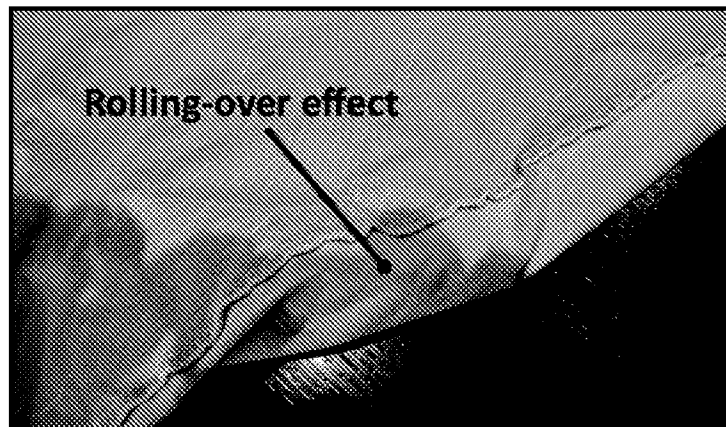
THE PRESENT . . .

...Furthermore, this uneven shrinkage of 3 different types of fabric also caused a “rolling-over” effect of either the Barrier or the Surface material. (Examples below)

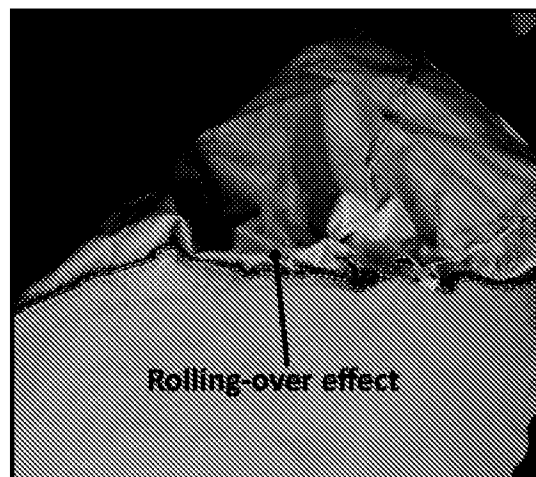
Example 1:



Example 2:

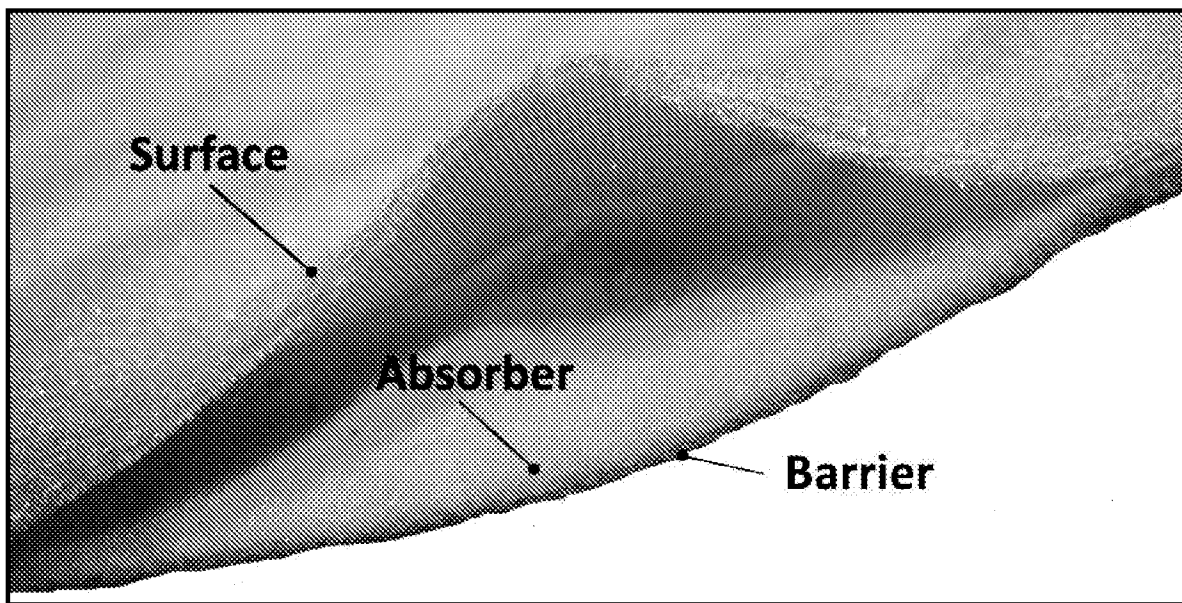


Example 3:



THE PRESENT . . .

Further development saw the substrate and Barrier layer fused to the Absorber, Surface face that goes up against the skin was still mechanically stitch-quilted to the Absorber. This would cause the Surface and Absorber to shrink at a different rate causing occasional bubbling and potential skin irritation points.



...What will the future hold?

The Answer:

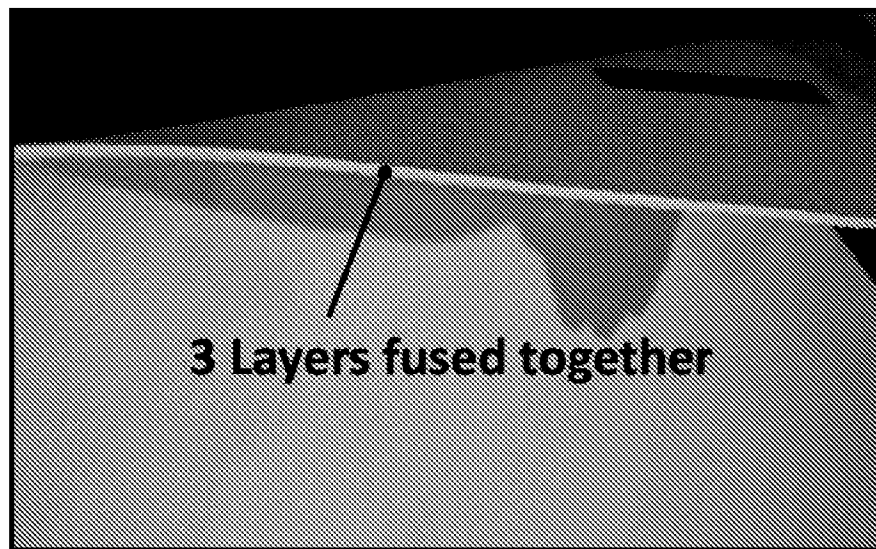
The future of Patient Underpads is one where all 3 layers are fused together: Surface to Absorber and Absorber to Barrier. This NEW procedure will eliminate shrinkage and pilling, and therefore increase patient comfort and revolutionize the Patient Underpad Market.

THE FUTURE...IS HERE!

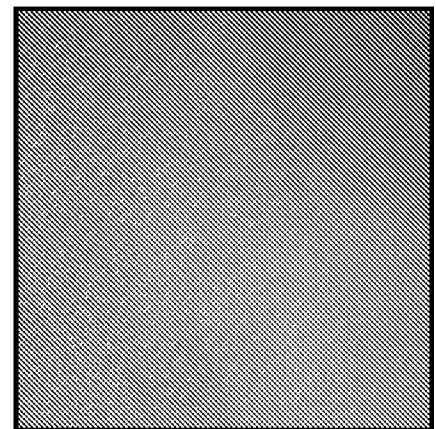
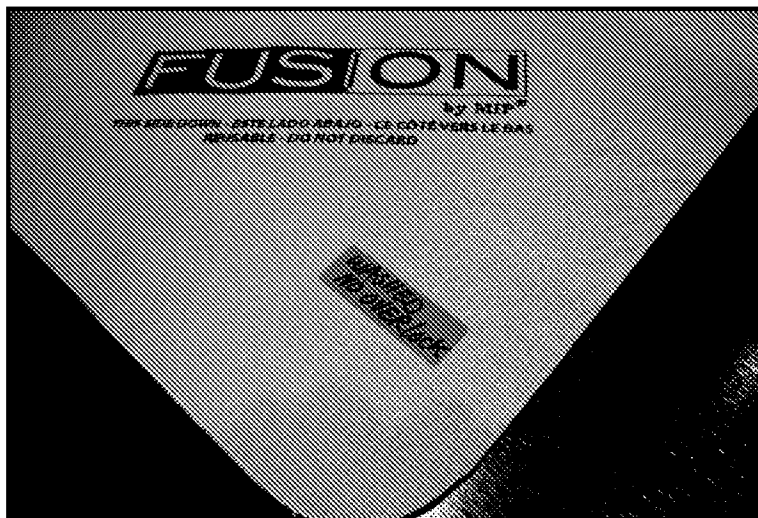
DermaCare Fusion

Patient Underpad

3 layers fused together:



Non-quilted Surface:



DermaCare Fusion

By MIP

The Future of Patient Underpads

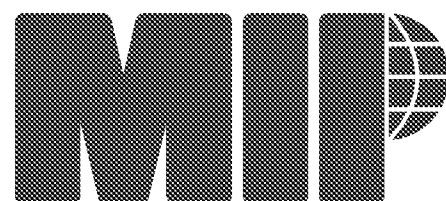
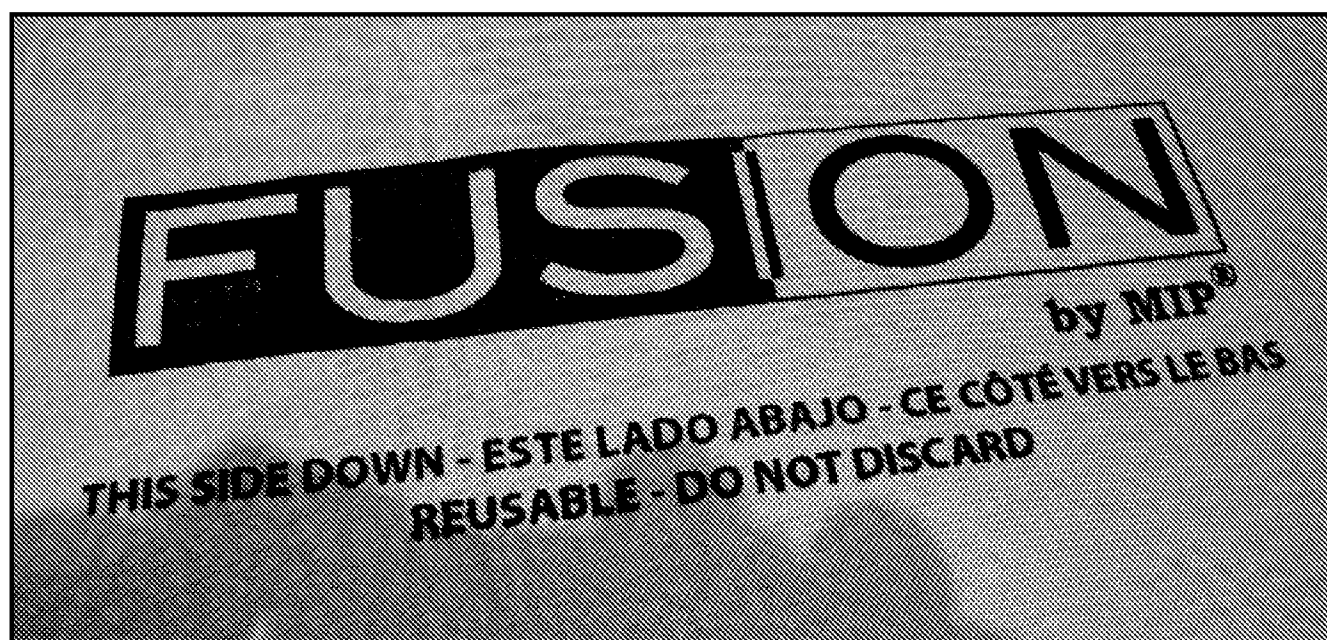
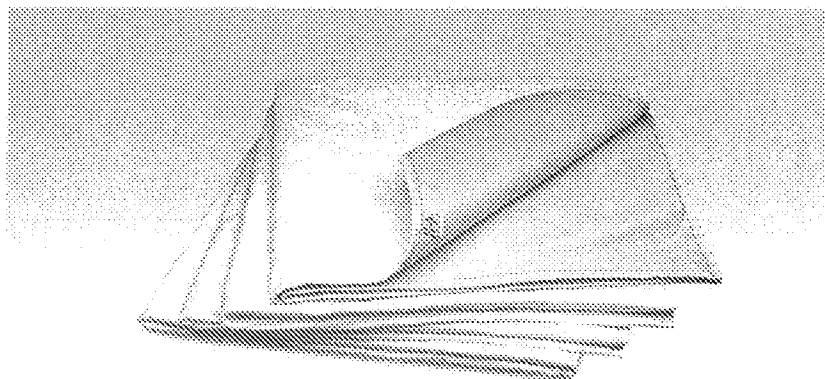


EXHIBIT D

Medline Sofnit 200 Underpad - Durability at a Great Price

A mainstay in many facilities, this underpad is a more economical version of our Sofnit 300 pad. It features lighter weight cotton/poly face fabric that offers good stain resistance and high heat resistance during drying. The total weight of this pad is lower than many other styles, resulting in lower processing costs. Equipped with a pink Vintex barrier.



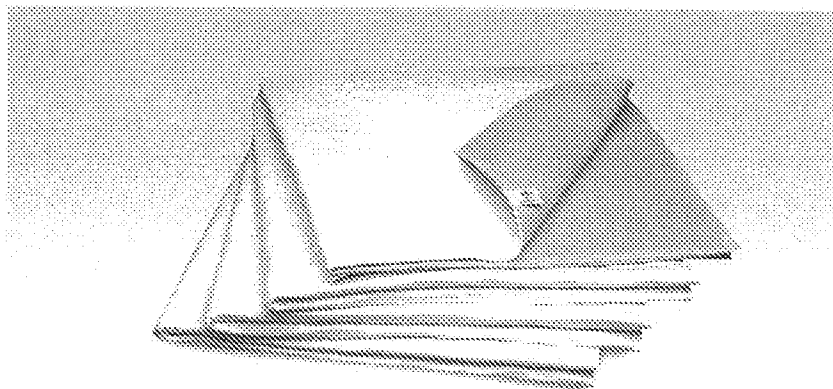
Item No.
MSC013000

Description
32" x 36"

Pkg
2 dz/cs

Medline Sofnit 300 Underpad - The Number One Selling Underpad in Health Care

Our best-selling underpad is a proven winner. It features a soft, durable face fabric of Ibex® and a moderate-duty poly/rayon soaker. Made to withstand 300 launderings, Sofnit 300 underpads have a very low cost per use.



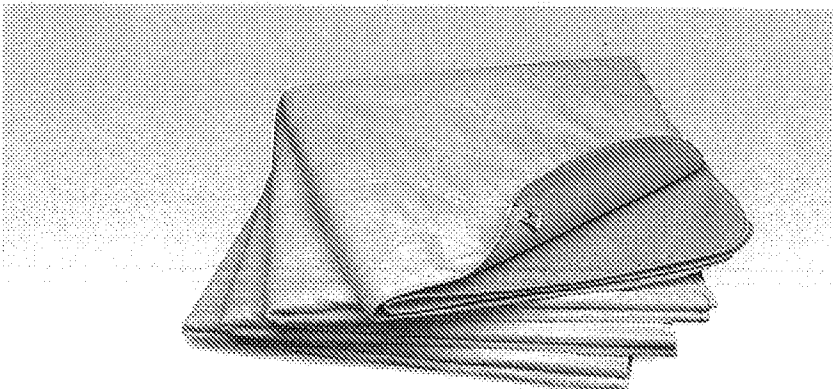
Item No.
MSC015000

Description
34" x 36"

Pkg
2 dz/cs

Triumph® Underpad - Constructed with Durability and Absorbency in Mind

This popular underpad provides a good combination of durability and performance. Its 2 x 1 twill-weave face fabric is exceptionally strong, and a thin heavy-duty poly/rayon soaker offers excellent absorbency. Triumph underpads have a Vintex® barrier and rounded corners to reduce abrasion.



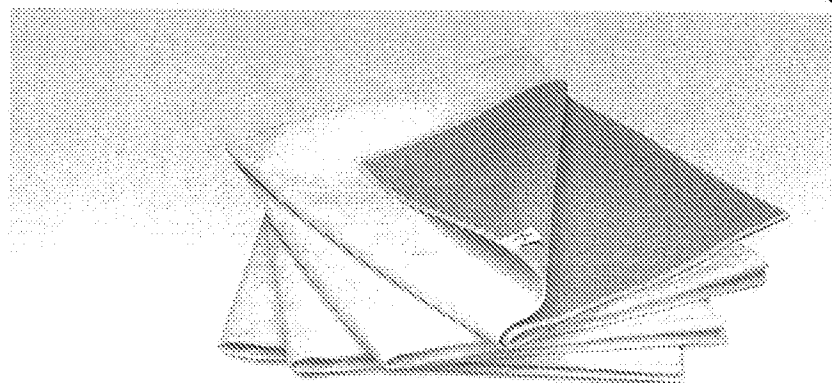
Item No.
MSC016000

Description
34" x 36"

Pkg
2 dz/cs

Medline Select Underpad - Our Lowest Cost Per Use Underpad

Durability, quality and dependability all at one great, low price. Equipped with a moderate-duty soaker, a tough twill-weave facing and a solid Vintex vinyl knit barrier, the new Medline Select underpad is the perfect choice for those looking to greatly reduce both acquisition and laundering costs.



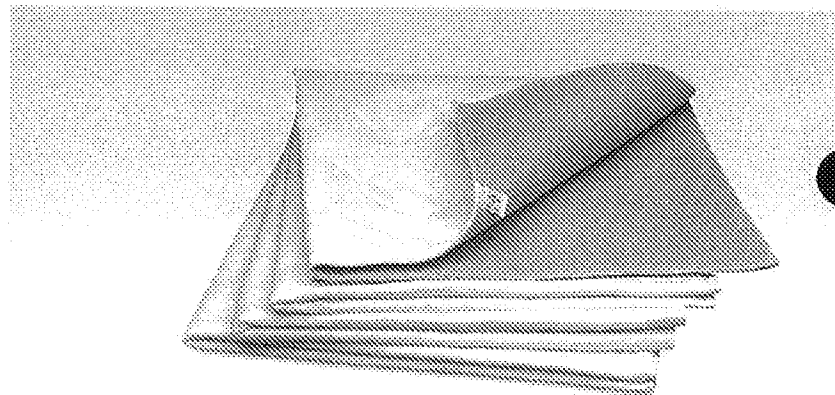
Item No.
MSC217000SL

Description
32" x 36"

Pkg
2 dz/cs

Maxima Underpad - Designed for Stain Resistance and Comfort

Deluxe brushed polyester face fabric is extremely soft against tender skin; it's also specially treated to resist stains. Other features include a Medline logo jacquard Vintex barrier and a heavy-duty poly/rayon soaker. Non-slip barrier helps keep the pad in place.



Item No.
MSC218000

Description
34" x 36"

Pkg
2 dz/cs

Sofnit 300 with Tartan Print Underpad - Perfect Combination of Patient Dignity and Performance

With its Tartan plaid printed colorfast ibex facing, this underpad makes stains less noticeable. A moderate-duty poly/rayon soaker and non-slip, green Medline logo jacquard Vintex barrier make this pad ideal.



Item No.
MSC015000P

Description
34" x 36"

Pkg
2 dz/cs



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COMPLYTM

PATENT PENDING

Ultimate Quilted Pads

Choose The Ultimate In Patient Care

Two years ago, our ComPlyTM fabric technology revolutionized the level of performance available in incontinent care products and redefined the standard for skin care. Now, our ComPly Ultimate quilted pads break new ground by providing the ultimate in comfort and nursing convenience at a significantly lower cost per use than disposables or any other reusables.

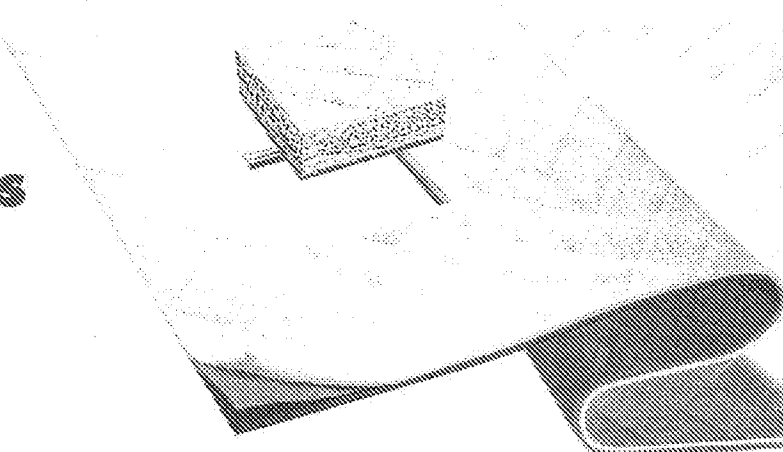
By responding to nursing needs with refined engineering and a commitment to continuous quality improvement, Standard Textile has created a product that is distinctly different. Just take a look at how we've addressed the perpetual problems you may have experienced with incontinent care products.

We have **quilted** our ComPly fabric and laminated it to a technologically superior barrier, creating a unique **one-piece** pad. This construction provides a non-bunching, non-curling, lightweight pad with a stable, textured non-slip barrier. Now you receive the ultimate in comfort in a product already known for its superior performance.

Maximize Comfort

Our new ComPly Ultimate quilted pads provide a level of comfort never before seen in today's health care market.

- * ComPly fabric technology **wicks** away moisture, creating a **dry**, comfortable surface within minutes.
- * **One-piece** quilted, laminated design eliminates bulk and bunching.
- * ComPly Ultimate quilted pads' superior absorbency holds more volume of liquid than any other comparable pad available.
- * Non-slip barrier fabric keeps pads in place, providing more comfort.
- * Thick, napped pile of top layer remains dry and soft for improved comfort.

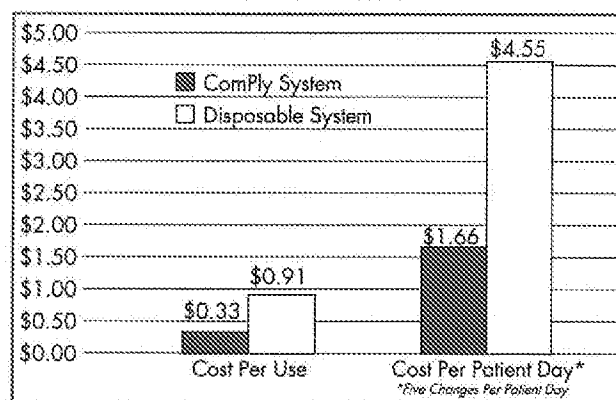


More Cost-Effective Than Disposables

ComPly Ultimate quilted pads provide the perfect alternative to costly disposables. More convenient to use and decidedly more cost-effective, ComPly pads create significant savings.

- * One ComPly Ultimate quilted pad gives more adequate bed coverage than multiple disposables.
- * Saves up to 50% over total cost of disposable system.
- * Reduces quantity of drawsheets, bath blankets and other linens used for absorbency.
- * Eliminates handling and separation costs of numerous disposables in linens and removes disposables that clog laundry equipment.
- * Create savings by reducing waste disposal costs.

ComPly Pad vs. Disposable Pad Cost Analysis



Based on cost analysis conducted at hospitals nationwide, using average costs of pads and additional linens required for 5 changes per patient day.

ComPly™ Ultimate Quilted Pads

Our ComPly Ultimate quilted pads' unique **one-piece** construction offers you the absolute best performance and durability.

- * Laminated barrier technology creates a unique, non-bunching one-piece pad.
- * Textured non-slip surface provides comfort and stability.
- * More durable than any incontinent product available.
- * Laminated construction decreases processing volume and costs.

Improve Nursing Convenience

ComPly Ultimate quilted pads were designed with your nursing staff in mind. More than any other pad available, our pads assist your nursing staff with lightweight, easy-to-handle, time-saving convenience.

- * Keeps beds dry by fully absorbing fluids and reducing or eliminating leakage.
- * Single pad per bed simplifies bed make up and saves time over disposables.
- * Reduces skin breakdown.

Let Us Show You The Difference

Provide the best in care by using ComPly Ultimate quilted pads. Our combination of ComPly fabric technology and our unique laminated, **one-piece** construction promises you the lightest weight and quickest drying available in a reusable pad. And you can enjoy this superior performance at less than half the cost per use of disposables.

Judge for yourself. Please take a look at the provided miniature pad sample to see the difference. Call your Standard Textile Sales Consultant for a comprehensive cost analysis and valuable product in-service information. Call toll-free today: **1-800-999-0400**.

ComPly Excel Quilted Pads

Our ComPly Excel quilted pads provide comfort, performance and durability by combining conventional construction and quilted ComPly technology.

- * Sewn, two-piece construction.
- * Textured, durable vinyl barrier.

Ultimate And Excel Product Specifications

Both ComPly Ultimate quilted pads and ComPly Excel quilted pads are available in **all** the following sizes:

- * 18"x 24", 24"x 30", 30"x 33", 30"x 36"

Make The Environmentally Responsible Choice

As regulation of solid waste and concern for our environment continue to affect health care issues, ComPly Ultimate quilted pads offer you a cost-effective way to reduce the negative impact of disposables on our environment.

- * Reduces your facility's contribution to the solid waste stream.
- * Places human waste in the wastewater system that was designed to handle it properly.
- * Reduces the amount of packaging waste.
- * Makes your facility less vulnerable to the impact of future landfill, incineration and solid waste legislation.
- * Reduces environmental impact.



**STANDARD
TEXTILE**

INNOVATORS IN HEALTH CARE
SINCE 1948

Standard Textile Co., Inc.
One Knollcrest Drive
P.O. Box 371805
Cincinnati, Ohio 45222-1805
(Toll Free) 1-800-999-0400
(Fax) 513-761-0467



standardtextile
HEALTHCARE

TruVal UnderpadTM

Kaiser Horizontal Wicking Rate Test

	TruVal	Ibex	Brushed Polyester
ZONE 1	4	4	4
ZONE 2	12	16	13
ZONE 3	34	186	123
ZONE 4	190	1055	2100

Values shown indicate time, in seconds, for 250 ml of liquid to reach outer edge of each zone.

Leveraging the power of fiber science

TruVal reusable underpads incorporate an entirely new class of performance designed polymer fibers known as Capillary Surface Materials. These novel cross-section geometry fibers are utilized in the critical outer portion of the underpad, facilitating extraordinary wicking performance and moisture management capability. This proprietary reservoir layer is complemented by the use of high airflow, quick drying, and soft mesh face fabric, providing for a skin contact surface that is both functional and truly comfortable.

To minimize shear and friction concerns and ensure extended product life, this unique quilt package is laminated to a high performance, capped, non-slip barrier backing. TruVal reusable underpads capitalize on the benefits of cutting-edge fiber technology combined with advanced automated fabrication methods to deliver a genuinely new, better, and more cost-effective solution.

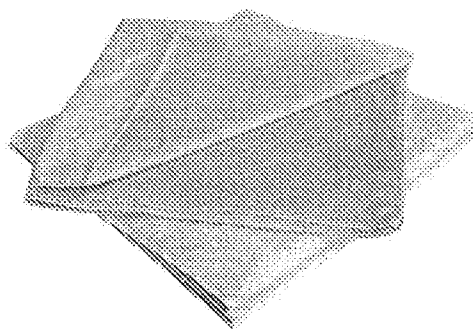
Zone 4

Zone 3

Zone 2

Zone 1

Tufftex Underpad

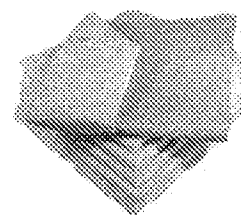


Tufftex Underpads are performance-based underpads designed for durability and high absorbency. The 80% cotton 20% polyester surface fabric is the **STRONGEST** surface fabric available at Absorb-Plus. This durable fabric is quilted to our 7-ounce soaker and offers the buyer a high degree of confidence in product integrity and quality.



Technical Data

Surface fabric : 80% cotton / 20% polyester
Soaker : 7 oz. polyrayon
Barrier : Soft-Knit



Tufftex Underpads

Style 117610 : 36" x 44" (2 dz/cs) "Allnighter®"
Style 117620 : 34" x 36" (3 dz/cs)
Style 11762T : 72" x 34" (2 dz/cs)

with
Tuck-in-Strips
Style 11762T



www.absorb-plus.com

1-888-747-7587
(514) 345-9770

ALEGRA® PREMIUM COMFORT PADS



- * UNBEATABLE COMFORT
- * SUPERIOR PERFORMANCE
- * LONG LASTING DURABILITY
- * DATE CODED LABEL
- * COST EFFECTIVE
- * PATENTED 5 LAYER DESIGN

THE ALEGRA® IS THE PREMIUM UNDERPAD ON THE MARKET TODAY. YOU CAN COUNT ON THE ALEGRA® FOR MORE PROVIDER AND RESIDENT BENEFITS THAN ANY OTHER PAD. THE ALEGRA® PREMIUM COMFORT PAD WILL OFFER YOUR RESIDENTS MORE COMFORT THAN ANY OTHER PAD. OUR PATENTED (USA #4,216,774) FIVE LAYER QUILTED DESIGN DELIVERS REAL IN-SERVICE SOLUTIONS FOR ANY FACILITY. REVOLUTIONARY FIBERS AND PRECISION ENGINEERING PROVIDE COMPLETE PROTECTION IN ONE PAD. THE DURABILITY OF ALEGRA® ASSURES COMFORT AND CAN HELP PROMOTE HEALTHY SKIN FOR RESIDENTS. OUR ALEGRA® PREMIUM COMFORT PAD TRULY DEMONSTRATES THAT TRUE VALUE COMES FROM A QUALITY PRODUCT. THE ALEGRA® IS A PATENTED FIVE-LAYER DESIGN THAT INCLUDES A LEAK-PROOF PVC BARRIER TO CONTAIN LIQUIDS, AN EXTRA THICK ABSORBENT FOUR LAYER QUILT, SERGED WITH A TRUE SAFETY STITCH, AND THEN BOUND WITH A COATED 200 DENIER NYLON BINDING FOR ADDED LEAK PROTECTION, LONGER LIFE, AND A MORE ATTRACTIVE APPEARANCE. CALL NOW TO ORDER A COUPLE OF DOZEN ALEGRA® FOR THOSE HARD TO PLEASE RESIDENTS, THOSE WHO VOID HEAVILY, OR THOSE WITH SENSITIVE SKIN.

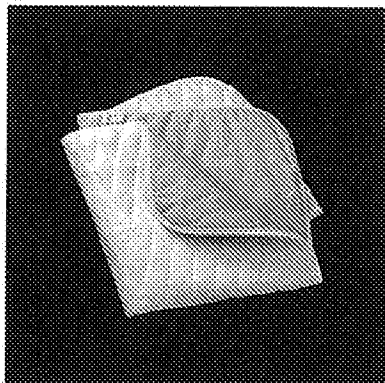
PROUDLY MADE IN THE USA.

ITEM #	CUT SIZE	BARRIER COLOR	CASE PUT UP	CASE WEIGHT
6967	36X36	GREEN	1 DZ	24 LBS
6961	28X36	GREEN	1 DZ	22 LBS
6978	24X34	GREEN	1 DZ	20 LBS
6962	18X20	GREEN	2 DZ	16 LBS

ALSO PACKAGED INDIVIDUALLY IN AN ATTRACTIVE, RETAIL ORIENTED SLEEVE, PERFECT FOR DME DEALERS, HOME HEALTH OUTLETS, DRUG STORES OR MAIL ORDER CATALOGS. LAY AN ALEGRA® NEXT TO A REGULAR UNDERPAD AND ASK YOUR CUSTOMERS WHICH PAD THEY WOULD RATHER THEIR FAMILY MEMBER HAVE TO LAY ON AND THEY WILL PICK THE ALEGRA® NEARLY EVERY TIME.. CALL NOW TO ORDER A DOZEN OF EACH SIZE.

ITEM #	CUT SIZE	BARRIER COLOR	CASE PUT UP	CASE WEIGHT
6963	36X36	GREEN	12/CS	26 LBS
6964	28X36	GREEN	12/CS	22 LBS
6965	18X20	GREEN	12/CS	8 LBS

PREM-AIR COMFORT PAD



- * UNBEATABLE COMFORT
- * SUPERIOR PERFORMANCE
- * LONG LASTING DURABILITY
- * DATE CODED LABEL
- * COST EFFECTIVE
- * PATENTED 5 LAYER DESIGN

THE PREM-AIR™ IS SECOND ONLY TO THE ALEGRA® PREMIUM COMFORT PAD WHEN IT COMES TO OFFERING YOUR RESIDENTS MORE COMFORT THAN STANDARD UNDERPADS. OUR SPECIAL FOUR LAYER QUILTED DESIGN DELIVERS SUPERIOR ABSORBENCY WITH A THICKER, MORE COMFORTABLE STYLE. THE DESIGN OF THE PREM-AIR™ COMFORT PAD ASSURES COMFORT FOR YOUR RESIDENTS. OUR PREM-AIR™ COMFORT PAD DEMONSTRATES THAT TRUE VALUE COMES FROM A QUALITY PRODUCT. THE PREM-AIR™ INCLUDES A LEAK-PROOF PVC BARRIER TO CONTAIN LIQUIDS. PROUDLY MADE IN THE USA.

ITEM #	CUT SIZE	BARRIER COLOR	CASE PUT UP	CASE WEIGHT
6562	18X20	GREEN	2 DZ	16 LBS
6550	30X36	GREEN	1 DZ	20 LBS
6560	34X36	GREEN	1 DZ	22 LBS

"THE LONGEVITY OF ALEGRA® MAKES IT MUCH EASIER FOR ME TO STAY WITHIN MY BUDGET. IT TAKES A LOT TO STAIN THE ALEGRA® UNDERPAD. THE STAFF LIKES THE ABSORBENCY AND THE FACT THAT THEY DON'T LEAK. THE THICK ALEGRA® UNDERPADS DON'T TAKE ANY LONGER TO DRY THAN THE SKINNY PADS"

R.M., MANITOWOC, WISCONSIN

I HAVE DONE BUSINESS WITH LANCHA TEXTILES, INC. FOR MANY YEARS. I HAVE TRIED OTHER SUPPLIERS FOR MY INCONTINENCE PRODUCTS, BUT I HAVE ALWAYS COME BACK TO LANCHA TEXTILES. LANCHA TEXTILES IS THE KIND OF COMPANY THAT REALLY TAKES CARE OF ITS DISTRIBUTORS. THEY OFFER MY COMPANY THE PERSONAL TOUCH I NEED TO BE COMPETITIVE.. I CAN FIND LOWER PRICES OUT THERE FROM BIGGER COMPANIES, BUT LANCHA TEXTILES OFFERS ME THE LITTLE THINGS I ASK FOR WITHOUT COMPLAINT. IF I WANT A SPECIAL COLOR BARRIER ON A BRIEF, OR BINDING ON MY UNDERPADS, THEY WILL WORK WITH ME TO MAKE THE PRODUCT THE WAY I NEED TO SATISFY MY CUSTOMERS. I WOULD RECOMMEND LANCHA TEXTILES TO ANY DISTRIBUTOR OUT THERE WHO WANTS THAT EXTRA LEVEL OF SERVICE THAT IS SO HARD TO FIND IN TODAY'S MARKET.

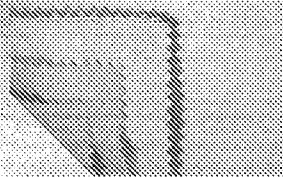
KEN C.

Protection maximale en tout temps!

GERITEX-PLUS® sait comment adoucir votre vie et celle de vos bénéficiaires! Grâce à la combinaison gagnante de ses composantes, GERITEX-PLUS® est passé maître dans l'art de la douceur, de l'absorption, du confort et de l'économie.

La douceur des tissus employés contribue au bien-être en évitant les irritations cutanées et les risques d'escarres. GERITEX-PLUS® est un produit anallergique qui a fait ses preuves. Une protection accrue et une capacité maximale d'absorption sont notre défi! Notre solution: une toile imperméable hydrofuge fabriquée au Canada selon les plus hauts standards de qualité. Un double résultat: le confort de vos bénéficiaires est assuré et votre tâche est simplifiée! GERITEX-PLUS®, sensible aux problèmes de l'environnement, porte une attention particulière à la qualité et à la durabilité des matériaux utilisés. Testé pour subir de fréquents lavages institutionnels, résistant à l'autoclave, GERITEX-PLUS® est un produit intelligent, réutilisable, non jetable et économique.

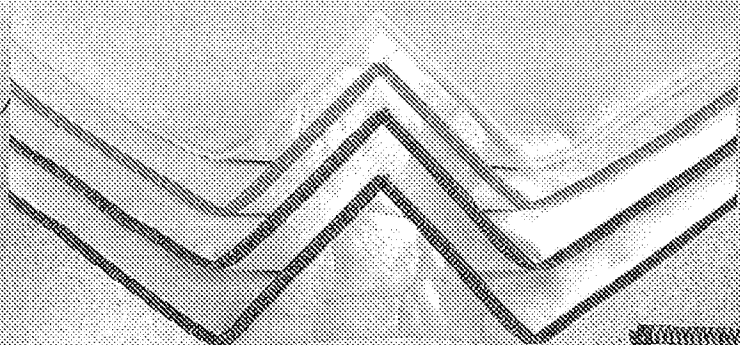
GERITEX-PLUS®



À... laissez le piqué!

Qu'on l'appelle alaise, piqué, ou qu'importe, il n'y a qu'un vrai **GERITEX-PLUS®**!

GERITEX-PLUS® offre une gamme de produits conçus pour répondre avant tout à vos critères de satisfaction. Toutes particularités sur la composition et les dimensions de votre GERITEX-PLUS® sont disponibles sur demande.



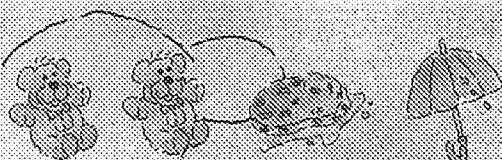
GERITEX-PLUS® régulier

- 43 x 61 cm (17 x 24 po) style P43
- 58 x 86 cm (23 x 34 po) style P58
- 76 x 86 cm (30 x 34 po) style P76
- 86 x 91 cm (34 x 36 po) style P86



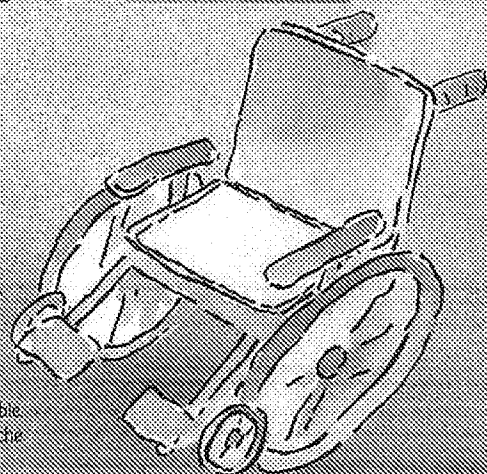
GERITEX-PLUS® matelassé

- 43 x 61 cm (17 x 24 po) style PM43
- 58 x 86 cm (23 x 34 po) style PM58
- 76 x 86 cm (30 x 34 po) style PM76
- 86 x 91 cm (34 x 36 po) style PM86



GERITEX-PLUS® matelassé avec bourre

- 43 x 61 cm (17 x 24 po) style PMB43
- 58 x 86 cm (23 x 34 po) style PMB58
- 76 x 86 cm (30 x 34 po) style PMB76
- 86 x 91 cm (34 x 36 po) style PMB86

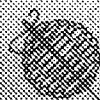
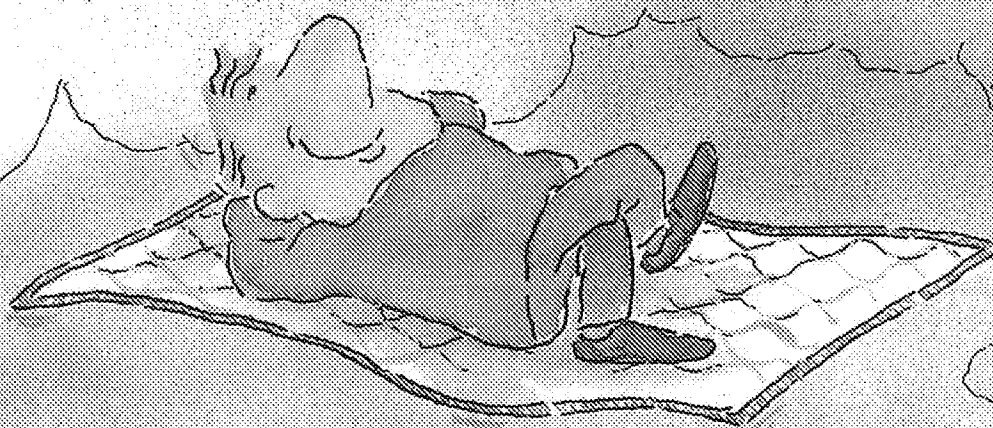


* Tolérance de plus ou moins 2,5 cm (1 po) du produit fini est considérée acceptable.

** Une bordure de couleur différente selon les dimensions vous simplifiera la tâche.

Le septième ciel du confort!

GERITEX-PLUS®

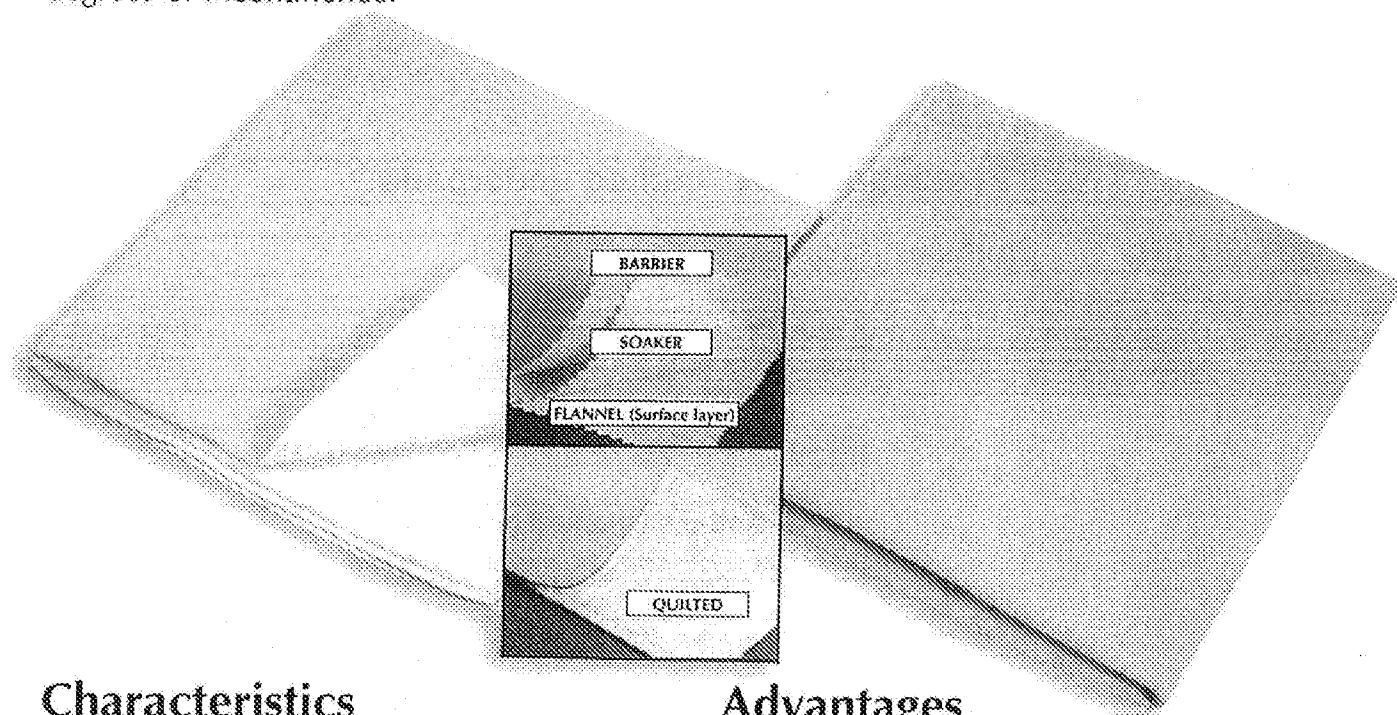


W. Laframboise Ltd.

4487, boul. Des Grandes Prairies
St-Léonard, Qué. (Canada) H1R 1A5
Tél. (514) 323-8551 • Fax (514) 323-8638

"3 in 1" Underpads

The Protection Plus™ underpad for incontinent persons is extremely soft, absorbant, impermeable and replaces all other underpads. They are available in different sizes for all degrees of incontinence.



Characteristics

BARRIER: High quality waterproof vinyl.
Weight: 240 gr/m² - 270 gr/m² according to various qualities - Colours: Maize or mint green

ABSORBANT SOAKER: A special blend of 60% polyester, 40% viscose fibers which is treated to eliminate all pilling. Absorbs up to 1.4 ml of fluid - Weight: 235 gr/m²

SURFACE: The flannel material is a blend of 80% cotton, 20% polyester. Weight: 195 gr/m²

UNDERPAD: Available quilted surface layer brushed or unbrushed with round corners to give a perfect finish.

3 STYLES:

DELUXE - DURABLE - STANDARD

Size: 76 x 86 cm

86 x 91 cm

Other sizes available upon request.

Advantages

ELIMINATE: The necessity of using a rubber sheet, a draw sheet and a regular underpad.

RESPECT: Environmental friendly contrary to disposable products.

COMFORTABLE: Eliminate the excess of heat or perspiration.

ECONOMIC: Can be re-used several times.

RESISTANCE SUPERIOR: Due to the strenght of the underpads, the professional may also use it to move or lift the resident.

**George
Courey**

Inc.

www.georgecourey.com

Location of our warehouses in Canada

Montreal

800-361-1087

Toronto

800-387-3501

Winnipeg

800-279-9350

Calgary

877-901-1756

GEORGE COUREY INC.

www.georgecourey.com

November, 2002

SPECIFICATION SHEET

PRODUCT:	"Protection plus" quilted underpads
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COMPOSITION:	Surface:	3 Options available
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IBEX - brushed flannel fabrics

80% cotton, 20% Polyester - Weight: 195gr/m2

T140 - Sheeting, 50% Cotton, 50% polyester

100% Anti-pill Brushed polyester

Very fast drying time, Aesthetically appealing

Absorbent:	60% Polyester, 40% Viscose - Weight: 235gr/m2
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Barrier:	100% Liquid Proof Polyester Knit Laminated to vinyl
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CHARACTERISTICS:	Quilted round corner construction Resistant to heat Absorbant layer Fast drying time Chlorine and stain resistant Durable Other sizes available upon request
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PRODUCT CODE:

SIZES	FLANNEL	SHEETING	POLYESTER
34X36" (86X91CM)	#C 902I	#C 902M	# C902P
34X45" (86X115cm)	# C 905I	#C 905M	# C905P

For more info:

Montreal	Toronto	Winnipeg	Calgary	Edmonton	Vancouver
800-361-1087	800-387-3501	800-279-9350	877-901-1756	888-436-3480	877-936-3366